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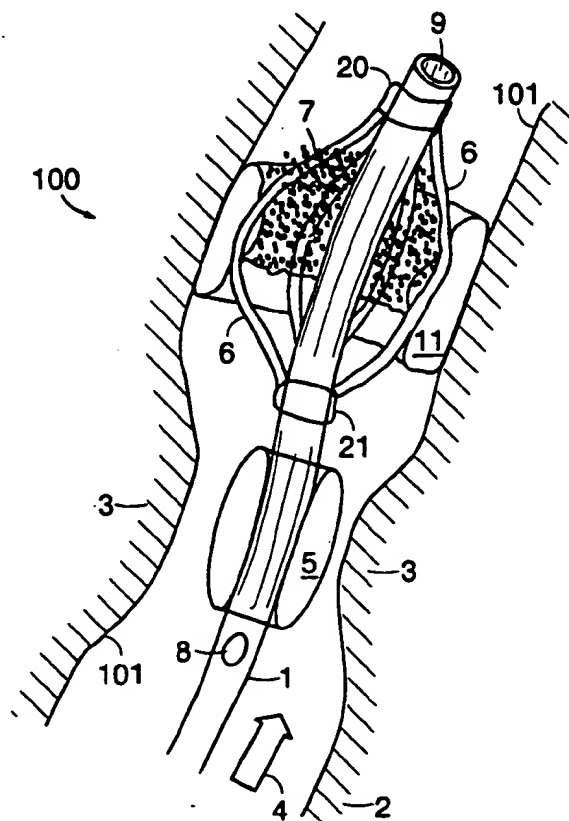
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: <b>PCT/US98/10220</b></p> <p>(22) International Filing Date: <b>15 May 1998 (15.05.98)</b></p> <p>(30) Priority Data:  60/046,777      16 May 1997 (16.05.97)      US  60/057,439      2 September 1997 (02.09.97)      US</p> <p>(71)(72) Applicants and Inventors: <b>GERTLER, Jonathan [US/US];</b>  16 Greenridge Road, Weston, MA 02193 (US). <b>KAMM, Roger [US/US];</b> 31 Nonesuch Road, Weston, MA 02193 (US).</p> <p>(74) Agents: <b>SUNSTEIN, Bruce, D. et al.; Bromberg &amp; Sunstein LLP,</b> 125 Summer Street, Boston, MA 02110-1618 (US).</p>	<p>(81) Designated States: <b>CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</b></p> <p><b>Published</b>  <i>With international search report.</i></p>	

(54) Title: CATHETER-FILTER SET HAVING A COMPLIANT SEAL

## (57) Abstract

A catheter-filter set in an embodiment may be used in a vas through which a biological fluid may flow. This embodiment includes a tubular member, having a lumen disposed along its length and an insertion end for insertion into the vas. The lumen defines a longitudinal axis and a radial direction perpendicular thereto. The embodiment also has a filter, coupled to the tubular member and having a circumference, for trapping undesired particles. Finally, the embodiment includes a resilient member, having compliance in the radial direction, disposed circumferentially about the filter and, when deployed in the vas, forms a seal against the interior wall of the vas. Other embodiments are also provided.



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**CATHETER-FILTER SET  
HAVING A COMPLIANT SEAL**

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Technical Field

The present invention relates to catheter-filter sets, including those for use in angioplasty and other procedures.

Background Art

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A large number of medical procedures utilize catheters. A catheter is defined herein and within the appended claims as a tubular, flexible instrument for insertion into a body cavity. Catheters may facilitate the withdrawal or introduction of fluids or other substances and may, in combination with other coupled components, perform a variety of other useful functions.

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Catheters coupled with inflatable balloons provide the means to facilitate the unblocking of and the relief of constriction within various body passageways and vessels. Such angioplasty procedures can replace other more invasive surgical procedures and provide acceptable solutions to correct life threatening conditions. However, these procedures carry a risk of serious secondary

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problems associated with the transmission of unwanted material downstream of the operative site. Any material, such as plaque built up in arterial vessels, which does not adhere to the interior vas wall or is in another way removed from the vessel following treatment becomes a likely source of downstream blockage.

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In arterial angioplasty, embolic ischemic damage distal to the angioplasty site is a major complication of the procedure. Mobile arterial plaque is a major factor linked with ischemic stroke or end organ/limb infarction. In particular, carotid

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artery angioplasty is not a favored practice at present due to the risk of emboli and resulting stroke.

Some catheters coupled with downstream filtering capability have been previously disclosed. Several utilize wire mesh filters which are generally not  
5 compliant and do not accommodate localized changes in vessel diameter and shape which may be caused by on-going fluid flow restoration and pulsatility. Other designs contain deployment structures which may make insertion prior to and retraction after completion of a procedure problematic or unduly risky.

Typical prior art catheter arrangements are disclosed in United States  
10 patents 4,723,549; 4,794,928; 5,662,671; and 5,695,519. These documents are hereby incorporated herein by reference.

#### Summary of the Invention

Various embodiments of the present invention solve problems of the prior art by providing radial compliance to accommodate localized changes in vessel  
15 diameter and shape which may be caused by on-going fluid flow restoration and pulsatility. Furthermore, some embodiments of the invention provide a device that is biased to return to its lowest profile condition in the absence of active operator input to facilitate making arterial angioplasty, particularly in the cerebral and coronary beds, more fail-safe. Various embodiments of the invention  
20 avoid asperities or protrusions which can traumatize or otherwise damage or irritate interior vas walls. Similarly various embodiments provide for cushioning of the filter element against the vas wall when it is deployed. This cushioning effect is balanced with the requirement of effective sealing of the vas to prevent any unwanted downstream flow of matter.

25 Accordingly, in a first embodiment of the invention there is provided a catheter-filter set for use in a vas through which a biological fluid may flow. This embodiment includes a tubular member, having a lumen disposed along its length and an insertion end for insertion into the vas. The lumen defines a longitudinal axis and a radial direction perpendicular thereto. The embodiment  
30 also has a filter, coupled to the tubular member and having a circumference, for trapping undesired particles. (Unless the context otherwise requires, the term

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"particles" as used in this description and the accompanying claims refers to substances to be removed from a vas, and may include thrombotic material.) Finally, the embodiment includes a resilient member, having compliance in the radial direction, disposed circumferentially about the filter and, when deployed in the vas, forming a seal against the interior wall of the vas. In further  
5       embodiments, the resilient member may be inflatable, such as a balloon, or alternatively may be an O-ring or sleeve. The outer surface of the resilient member may form the seal with the interior wall or may otherwise effectuate the seal. In a related embodiment the resilient member is a balloon having an  
10       anterior for receiving an inflation fluid and a shape so that when the balloon is inflated there is provided a passageway permitting fluid flow through the filter. In accordance with another related embodiment, the balloon is toroidal in shape and may have anisotropic elasticity so that during inflation its interior cross-section expands relatively less than its radial extent. Alternatively or in addition,  
15       the catheter-filter set may include an elastic member coupled to the balloon and the tubular member for causing the balloon to be radially confined when not deployed. In yet another variation, regardless whether a balloon is utilized, the filter has a stowed position where the filter is radially confined and disposed in the lumen so that the catheter-filter set may be inserted into and removed from  
20       the vas, and a deployed position, where the filter is radially expanded.

Various embodiments of the present invention have a range of potential applications. The application of embodiments to angioplasty procedures will be apparent to those skilled in the art. In addition, through either standard open technique or laparoscopic technique, retrieval of common duct stones in the  
25       biliary tree is facilitated by catheter passage utilizing embodiments herein. Similarly, through either standard open technique or cystographic technique, retrieval of ureteral and bladder duct stones is, also, facilitated by catheter passage via endoscopic or surgical methods. A catheter coupled with an inflatable balloon may also be utilized to effect balloon sphincteroplasty and  
30       stone retrieval. Embodiments herein provide improved devices to effectively retrieve such stones and to avoid their further passage or migration downstream.

Embodiments herein may also be employable as a temporary filtering device for the vena cava. In the process of lytic treatment for deep venous thrombosis, there is a risk of clot ( thrombus) breaking loose and causing pulmonary embolism, a potentially fatal event. Although filters exist for vena  
5 cava use, these are permanent structures with attendant long term morbidity. Having an effective and retractable filter which is in place ... only for the time of significant risk, *i.e.*, during deep venous clot lysis, would allow protection from pulmonary embolism and avoidance of the long term sequelae of a permanent filter insertion.

10 Discussion of medical procedures and associated devices in this description may focus, for example, upon arterial (blood circulation), biliary, and ureteral systems. This focus in no way limits the applicability of embodiments herein to any and all other uses for catheters with filtration capability known to those skilled in the art.

15 In another embodiment, there is provided a catheter-filter set having a tubular member, which has a first lumen disposed along its length, an insertion end for insertion into and a retraction end for retraction out of the vas. The lumen defines a longitudinal axis and a radial direction perpendicular thereto. The embodiment also has a filter, coupled to the tubular member proximal to the  
20 insertion end, wherein the filter has a stowed position and a deployed position, and a non-inflatable actuator, coupled to the filter, for causing the filter to move from the stowed position to the deployed position, wherein, absent operation of the actuator, the filter is biased to be in the stowed position. In a related embodiment, the set also includes a vas conditions-modifying element located  
25 upstream from the filter; this element may be an angioplasty balloon. In yet another related embodiment, the tubular member has a second lumen having an inlet upstream from the vas conditions-modifying element and an outlet downstream from the filter, permitting unimpeded, downstream fluid flow to  
30 bypass the filter. In further embodiment, the set has a plurality of resilient ribs, each rib having a first end coupled to the tubular member, each rib also coupled to the filter, the ribs having a stowed condition in which they are parallel to the



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longitudinal axis and a deployed condition in which at least a portion of each rib is disposed radially outward from the tubular member. Each rib may have a second end slidably mounted on the tubular member and coupled to the actuator. The catheter-filter set may further include a resilient member, having  
5 compliance in the radial direction, disposed circumferentially about the filter and, when deployed in the vas, forming a seal against the interior wall of the vas.

In another embodiment in accordance with the present invention, there is provided a catheter-filter set having:

- 10 a. a tubular member, having a lumen disposed along its length, an insertion end for insertion into and a retraction end for retraction out of the vas, the lumen defining a longitudinal axis and a radial direction perpendicular thereto; and
- b. a filter, coupled to the tubular member proximal to the insertion  
end, wherein the filter has a stowed position wherein the filter is radially  
15 confined and disposed in the lumen so that the catheter-filter set may be inserted into and removed from the vas, and a deployed position, wherein the filter is radially expanded.

#### Brief Description of the Drawings

20 Figs. 1A and 1B are longitudinal views of a catheter-filter set, in the deployed and the stowed conditions, respectively, used in a vas as part of an angioplasty device and using a toroidal balloon according to an embodiment of the invention.

Figs. 2A and 2B are longitudinal views of a portion of a catheter-filter set,  
25 in the stowed and the deployed conditions, respectively, illustrating generally filter deployment according to an embodiment of the invention utilizing ribs for structuring the filter.

Figs. 3A and 3B are longitudinal views of a catheter-filter set, in  
accordance with a tether deployment embodiment of the invention, showing  
30 stowed and deployed conditions, respectively.

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Figs. 4A and 4B are longitudinal views of a catheter-filter set, in accordance with a balloon deployment embodiment of the invention, showing stowed and deployed conditions, respectively.

Fig. 5 is a longitudinal view of a catheter-filter set in accordance with an embodiment using balloon deployment wherein elastic bands bias the set in a stowed condition.

Figs. 6A and 6B are stowed and deployed conditions respectively of an embodiment similar to that of Figs. 4A and 4B, but wherein the ribs are normally twisted in a stowed condition, in which the embodiment is biased.

Fig. 7A is a cross-sectional view of a catheter-filter set in the deployed condition illustrating a balloon deployment design according to an embodiment of the invention in which the balloon has a passageway to permit fluid flow therethrough. Figs. 7B and 7C are longitudinal views of the same embodiment in the stowed and the deployed conditions, respectively.

Fig. 8A is a cross-sectional view of a catheter-filter set according to an embodiment of the invention, using for deployment a balloon 11 that is asymmetrically disposed with respect to the tubular member. Fig. 8B is a longitudinal view of the same embodiment in the deployed condition. Fig. 8C shows detail of the catheter-balloon interface.

Fig. 9 is a view of a catheter-filter set according to an embodiment of the invention utilizing a retractable O-ring.

Fig. 10 is a perspective view of a catheter-filter set according to an embodiment of the invention that is similar to the embodiment of Fig. 9, but utilizing a sleeve in lieu of the O-ring.

Fig. 11A is a perspective view of a catheter-filter set according to an embodiment of the invention utilizing a tethered O-ring, shown in the deployed condition. Fig. 11B is a longitudinal view of the same embodiment in the stowed condition.

#### Detailed Description of Specific Embodiments

Various embodiments of the catheter-filter set described herein address a number of shortcomings inherent in previous designs. Some desirable features

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for the filter portion of the set are that it be easily confined in a radial direction for ease of set insertion and removal, that it be capable of capturing and safely removing all particles flowing downstream in a vas, and additionally, it should be designed so as to minimize the risk of accidental deployment and to collapse  
5 into position for removal in the event of failure. It should be atraumatic to the native vas wall and should accommodate changes in vas diameter.

Figs. 1A and 1B are longitudinal views of a catheter-filter set, in the deployed and the stowed conditions, respectively, used in a vas as part of an angioplasty device and using a toroidal balloon according to an embodiment of  
10 the invention. Fig. 1A shows a catheter 1 inserted into a vas 2. The vas may be constricted or otherwise blocked at a location 3. Downstream fluid flow is indicated by arrow 4. An angioplasty balloon 5 affixed to the catheter and inflatable (by means well known in the art) is positioned proximate to location 3. During and after the angioplasty balloon 5 inflation process, unwanted particles  
15 may flow downstream from location 3. A plurality of resilient ribs 6 (four are shown in this view) are coupled to the catheter 1 by two collars, one collar 20 at a downstream end and the other collar 21 at an opposing, upstream end of the catheter. In this embodiment, one of collars 20 and 21 is fixed relative to the catheter 1 and the other of the collars is free to slide along the catheter 1. The ribs  
20 6 and both collars 20 and 21 are positioned at a location downstream from location 3 and the angioplasty balloon 5. A filter 7 is shown attached to the ribs 6 and to the catheter 1. A toroidal balloon 11, which is distinct from the angioplasty balloon 5, is attached to the ribs 6. In this embodiment, the toroidal balloon 11 is mounted approximately midway along the length of the ribs 6 and positioned  
25 radially outward from the catheter 1. (The filter 7 is represented in this figure and figures below by a dot or hash pattern; for clarity of representation, the dot or hash pattern is not shown to occupy the entire region occupied by the filter. It will be understood, however, that when deployed the filter, together with any accompanying structure, such as the balloon 11, will occupy the entire cross  
30 section of the vas so as to operate in an effective manner known in the art.)

Fig. 1B shows that, in accordance with the embodiment in the stowed condition, the ribs parallel to the longitudinal axis of the catheter 1 facilitating set 100 insertion into and retraction out of the vas 2 minimizing trauma to the vas wall 101. During insertion and retraction of set 100 and catheter 1 into and out of the vas 2, the uninflated toroidal balloon 11 is collapsed and radially confined against the ribs 6 and the uninflated angioplasty balloon 5 is collapsed against the catheter 1. As illustrated in Fig. 1A, when the toroidal balloon 11 is inflated (in accordance with means well known in the art), one of collars 20 and 21 slides toward the other collar causing at least a portion of each of the ribs 6 and the filter 7 to be disposed radially outward from the catheter 1. The toroidal balloon 11 effectively spans any radial distance between, on the one hand, the vas wall 101, and on the other hand, the ribs 6 with the expanded filter 7. The toroidal balloon 11 thus forms a compliant seal between the set 100 and the vas wall 101.

After this compliant seal has been established, the angioplasty balloon 5 may then be inflated to unblock the vas 2 at location 3. The deployed filter 7 may then capture unwanted particles flowing downstream during and after operation and subsequent deflation of the angioplasty balloon 5. After the procedure, the toroidal balloon 11 is deflated, and the set 100 returns to the position shown in Fig. 1B for retraction from the vas 2. Unwanted particles are trapped within the filter 7 and are safely removed from the vas 2 upon retraction of the set 100. Additionally, biasing components (for example, as discussed below in connection with later figures) may be used in connection with the set 100 to insure the return to the position shown in Fig. 1B after deflation of the toroidal balloon 11. These components may include, and are not limited to, elastic bands coupled to one or more elements of the ribs 6, the filter 7, and collars 20 and 21.

Also shown in Fig. 1A, an inlet port 8 is provided by the catheter 1 at a location upstream from the angioplasty balloon 5 and an outlet port 9 is provided downstream from the filter 7. The ports are in communication with a lumen of the catheter; the lumen may be the same as the lumen used for other purposes or may be a separate dedicated lumen. The result of this structure is an auto-perfusion pathway from inlet port 8 through a catheter lumen to the outlet port 9

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to permit the unimpeded flow of a quantity of fluid during the time in which the medical procedure is being performed. The feature is advantageous when deleterious results may occur from even short intervals of downstream fluid starvation or depletion. Hypoperfusion during angioplasty balloon inflation is

5 primarily relevant to the cerebral and coronary beds. Carotid artery angioplasty, in which the brain is immediately downstream from the location 3, is a prime example of a procedure benefiting from an auto-perfusion pathway. In many arterial applications, given the normal magnitude of blood pressures, there may be provided a lumen having an internal diameter of 1 to 2 mm. Even when blood

10 flow is not as high as normal, the reduced rate of flow may nevertheless significantly reduce the risk of tissue damage caused by a complete interruption of flow in the cerebral and coronary beds.

Figs. 2A and 2B are longitudinal views of a portion of a catheter-filter set, in the stowed and the deployed conditions, respectively, illustrating generally

15 filter deployment according to an embodiment of the invention utilizing ribs 6 for structuring the filter 7. Fig. 2A shows the ribs 6 and the filter 7 coupled to and juxtaposed with the catheter 1 in conjunction with the downstream collar 20. In Fig. 2B the ribs 6, which are resilient, are expanded radially from the catheter 1 to form a convex shape. The expanded ribs 6 support the filter 7 as shown.

20 Preferably, the ribs 6 are free from asperities. The ribs 6 may be made of any resilient material with sufficient rigidity to support and to enable deployment of the filter 7. The number of ribs 6 may be selected to be sufficiently large to facilitate a seal of the filter 7 with the interior wall of the vas 2 but not so numerous as to significantly obstruct fluid flow or convenient operation of the

25 set. In the embodiment of Figs. 2A and 2B, the ribs 6 are disposed radially outward from the filter 7. In other embodiments of the invention, the ribs 6 may be disposed radially inward from the filter 7, so that, when stowed, the resilient ribs 6 lie immediately adjacent to the catheter 1. Such other embodiments may deploy in a fashion analogous to opening of an umbrella. The ribs 6 may have

30 one free end as in Figs. 2A and 2B, or be coupled to the catheter 1 at both ends and bow in the middle for deployment as for example in Figs 1A and 1B. The

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filter 7 may beneficially be made of a porous, compliant material in a manner known in the art. Suitable materials may include, but are not limited to, woven nylon, plastic resins such as PTFE sold under the Teflon trademark by Dupont of Wilmington, Delaware, other woven polymer, porous silicone rubber and latex  
5 rubber. Suitable materials are sufficiently porous to permit a small downstream flow of fluid yet capable of collecting any dangerous particles. For example, calculations suggest that, for an arterial application, a woven material with a fiber porosity of 90% and a spacing of 200 microns may pose little impediment to normal blood flow while trapping undesirable particles..

10 Figs. 3A and 3B are longitudinal views of a catheter-filter set, in accordance with a tether deployment embodiment of the invention, showing stowed and deployed conditions, respectively. As shown in Fig. 3B, the ribs 6 of this embodiment are attached to the catheter 1 at both ends by collars 20 and 21. The upstream end collar 21 is free to slide along the catheter 1 while the  
15 downstream end collar 20 is fixed. Collar 21 is tethered with line 30 so that an operator can, by applying an upstream force to line 30 slide collar 21 downstream toward collar 20. This action urges the ribs 6 to form a convex shape and to expand radially from the catheter 1. As Figs. 3A and 3B show, tethering may be accomplished by attaching one end of line 30 to collar 21, feeding the line 30  
20 through a port 31 provided by the catheter 1 at a position downstream from collar 21. The line passes into a lumen of the catheter and exits the catheter 1 upstream at its retraction end. The ribs 6 may expand to the full radial extent of the vas 2. Other material, as discussed in connection with other figures, may be coupled to the ribs 6 proximate to their approximate midpoint in length to  
25 provide better sealing action and cushioning at the interface with the vas wall 101. (For example, the toroidal balloon of Figs. 1A and 1B may be employed; alternatively, any suitable resilient sleeve or O-ring may be utilized.) The ribs 6 will return to the stowed position of Fig. 3A, in accordance with the embodiment of the invention, with the elimination of the applied upstream force on line 30.  
30 This provides a set 100 which is biased to remain in and revert to the stowed position. Such bias provides for assured collapsibility upon retraction and offers

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a high degree of fail-safe operation by minimizing the chance of accidental deployment.

Another embodiment according to the invention provides a filter deployment technique using an inflatable toroidal balloon 11 with ribs 6 which have their upstream end uncoupled to the catheter 1. The stowed position is shown in Fig. 4A; the deployed position in Fig. 4B. Operation of this embodiment is similar to that of Figs. 1A and 1B with respect to the use of a toroidal balloon and to that of Figs. 2A and 2B with respect to the ribs 6. A tube 40 is provided for inflation fluid communication between a lumen disposed within the catheter 1 and the toroidal balloon 11. The opposing ends of tube 40 are, respectively, inserted and remain within ports 41, provided by the catheter 1, and 42, provided by the toroidal balloon 11. The ends of tube 40 may be secured in the ports 41 and 42 with adhesives or using other methods in a manner known in the art. The uninflated toroidal balloon 11, as shown in Fig. 4A is coupled to the upstream ends of the ribs 6 and juxtaposed with the catheter 1. As shown in Fig. 4B, with inflation of the toroidal balloon 11, the resilient ribs 6 expand radially from the catheter 1 to form a convex shape supporting the filter 7. At its most radially outward extent, the inflated toroidal balloon 11 effects a compliant seal between the set 100 and the vas wall 101. The toroidal balloon 11 may be made by wrapping fiber around it so that its expansion will be constrained in such a way that the diameter of its inflatable cross-section increases to a lesser degree than its radial (perpendicular to the catheter axis) dimension. In fact, this mode of inflation can be produced by any material that is anisotropic having a high stiffness (or Young's modulus) in the direction of the fiber wrapping and a low stiffness in the direction perpendicular to the wrapping. The inflation of the toroidal balloon provides the necessary structural rigidity needed to withstand the forces associated with downstream fluid flow (in particular, arterial blood flow) while the set 100 is in the deployed condition.

Fig. 5 is a longitudinal view of a catheter-filter set in accordance with an embodiment using balloon deployment wherein elastic bands 50 are employed to bias the set in a stowed condition. The bands 50 are coupled to an upstream collar

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51 and a second downstream collar 52. Both collars 51 and 52 are coupled to the catheter 1; the second downstream collar 52 is positioned at a distance farther downstream along the catheter 1 than collar 20 to which optional ribs 6 may be coupled. This embodiment provides a set 100 which is biased to revert to the  
5 stowed condition. On deflation of the toroidal balloon 11, the bands 50 act to force the balloon 11, the ribs 6, and the filter 7, with any entrapped particles within, to revert to the stowed condition for safe retraction.

Figs. 6A and 6B are stowed and deployed conditions respectively of an embodiment similar to that of Figs. 4A and 4B, but wherein the ribs are normally  
10 twisted in a stowed condition, in which the embodiment is biased. The ribs 6 (which are here differently shaded to permit differentiation in the figure), when in a relaxed, unstressed configuration, fit snugly about the catheter 1 bore in a helical arrangement, as shown in Fig. 6A. The filter 7 is gathered together inside the ribs while the cushioning balloon 11 lies outside the ribs 6 but deflated into a  
15 collapsed configuration. The ribs 6 in this embodiment are attached at both the upstream and downstream ends to collars 21 and 20 respectively. The collars 21 and 20 are constrained so as to prevent movement in the longitudinal direction, but the downstream collar 20 can be rotated by rotation of a stiff line 60 threaded through a lumen 61 of the catheter 1. Rotation of the downstream collar 20  
20 causes the ribs 6 to bow outward into the deployed position illustrated in Fig. 6B. Once deployed, the balloon 11 can be inflated to provide a resilient seal against the interior wall of the vas 101 while maintaining an open space between the balloon 11 and catheter 1 for fluid flow. Bowing of the ribs deploys the filter 7 attached to the inner surface of the balloon 11 so that it can function as a trap for  
25 debris released from an upstream site. Retraction of the ribs 6 occurs when the stiff line 60 is allowed to rotate back to its original position and the balloon 11 is deflated. The filter set is therefore biased closed in that when pressure is relieved from the balloon 11 and the torque exerted on the stiff line 60 is released, the ribs 6 and filter 7 revert to their stowed position.

30 Fig. 7A is a cross-sectional view of a catheter-filter set in the deployed condition illustrating a balloon deployment design according to an embodiment



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of the invention in which the balloon has a passageway to permit fluid flow therethrough. Figs. 7B and 7C are longitudinal views of the same embodiment in the stowed and the deployed conditions, respectively. In this embodiment, the inflation balloon 11 takes on the shape of two "Ds" back-to-back. The advantage  
5 of this embodiment is that the catheter 1 passes directly through the inflatable portion of the balloon 11, avoiding the need for a separate inflation line that might be prone to rupture because of its small diameter. Fig. 7A shows the balloon in a view along the axis of the vas 2 looking in the downstream direction. The catheter 1 can be seen passing through at the center, and is sealed to the  
10 balloon at the points where it passes through the balloon membrane. The catheter has a port inside the balloon 11 that is used for balloon inflation. The filter 7 is seen in Fig. 7A through the openings in the balloon 11 through which the fluid is free to flow. Fig. 7B shows the balloon 11 in the retracted or stowed position. Elastic bands 50 hold the deflated balloon 11, so that it is radially  
15 confined, tight against the catheter 1. The filter 7 is gathered together and held against the catheter 1 in part by the elastic bands 50. Deployment is accomplished by inflation of the balloon 11, a process that forces the balloon 11 into its double-D shape shown in longitudinal view in Fig. 7C. The inflated balloon 11 of Fig. 7C forms a flexible seal against the vas wall 101 and deploys  
20 the filter 7. The filter in this embodiment is firmly tethered to the catheter at its downstream end to aid in gathering the filter 7 to the catheter on balloon deflation. The balloon 11 is made from a flexible but relatively inextensible polymer so that on inflation, it takes the shape shown.

Fig. 8A is a cross-sectional view of a catheter-filter set according to an  
25 embodiment of the invention, using for deployment a balloon 11 that is asymmetrically disposed with respect to the tubular member. Fig. 8B is a longitudinal view of the same embodiment in the deployed condition. Fig. 8C shows detail of the catheter-balloon interface. This embodiment increases the area available for flow through the "doughnut hole" of the balloon 11 and, like  
30 the embodiment of Figs. 7A through 7C, avoids the need for a separate inflation tube connecting the balloon 11 with the catheter 1. In this embodiment, the

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catheter 1 passes through the toroidal balloon 11 at location 80 on its circumference; a seal is provided between the balloon 11 and the catheter so that the balloon can be inflated through a port as in the embodiment of Figure 7. In the stowed position, shown in Figure 8A, an elastic band 50 attached to the  
5 balloon 11 at a point diametrically opposite to the inflation site 80 draws the balloon 11 in the upstream direction. When and as the balloon 11 is deflated, it and filter 7 are collapsed radially against the catheter 1 bore under the force of the elastic band 50. Additional elastic bands may be optionally used on the downstream side to help gather together the filter 7 on deflation. The filter is  
10 deployed by inflation of balloon 11 through the port at location 80 as illustrated in Figure 8B. Balloon inflation also seals the balloon 11 in a flexible manner against the wall of the vas. In the process of balloon inflation, the catheter 1 is displaced off center toward the wall of the vas so as to increase the area available for flow. All flow still passes through the filter 7.

15 Fig. 9 is a perspective view of a catheter-filter set according to an embodiment of the invention utilizing a retractable O-ring. The downstream end of the catheter 1 is pictured at a location downstream of a suitable vas-modifying element. The filter 7 is fastened to an O-ring 90 which in turn, is coupled to a set of resilient ribs 6 (four of which are shown). When in the deployed position  
20 (shown) the ribs 6 are pushed out of the downstream end of the catheter 1. The resilience of the O-ring 90 (optionally, in combination with shape memory of the ribs 6) causes the ribs 6 to separate as the O-ring 90 deploys into its natural circular shape, producing a seal against the wall of the vas. In so doing, the O-ring 90 expands the filter 7 so that it can trap debris released from an upstream  
25 location. The filter 7 is returned to its original undeployed position by retracting the ribs 6 into the catheter 1, exerting a radially-inward force on the O-ring 90, causing it to buckle into a multi-lobed pattern with outside radial dimension much smaller than in the deployed position. The ribs 6 can be drawn into the catheter 1 by means of a stiff  
30 tether line 91 attached to the ribs 6 at their upstream end 92 within the catheter lumen. The tether line 91 must be sufficiently rigid that it can exert the force

- 15 -

needed to deploy the filter 7 and the O-ring 90. For ease of retrieval, the filter 7 can be sheathed by a second catheter that slides on the outer bore of the catheter 1, slipping over the buckled O-ring 90 and filter 7.

Fig. 10 is a perspective view of a catheter-filter set according to an embodiment of the invention that is similar to the embodiment of Fig. 9, but utilizing a cylindrical sleeve 93 in lieu of the O-ring 90. An advantage of the sleeve is that the filter 7 can be entirely contained within the sleeve 93 when the ribs and filter are in the retracted position, thus eliminating the necessity for a second catheter.

Fig. 11A is a perspective view of a catheter-filter set according to an embodiment of the invention utilizing a tethered O-ring, shown in the deployed condition. Fig. 11B is a longitudinal view of the same embodiment in the stowed condition. This embodiment shows that an O-ring 191 may be employed in situations in which the filter 7 is attached upstream of the end of the catheter 1. Deployment, in this embodiment, is accomplished when the operator relaxes the force applied by the line 121 which passes through the wall of the catheter 1 at point 122. The line 121 is attached to a collar 21 that can slide freely along the bore of the catheter 1. When force is relaxed, the resilience of the O-ring 191 that exerts a tension in a plurality of tether lines 200 (two are shown) pulls the collar 21 in the downstream direction. The O-ring 191, selected to be of an outer diameter when fully extended slightly larger than the normal diameter of the vas, provides a flexible seal against the wall of the vas when the tension force in tethers 200 is reduced. A filter 7 is attached around the circumference of the O-ring 191 and is deployed when the O-ring is allowed to expand to fill the vas. The O-ring 191 is also attached to a plurality of additional tethers 201 (two are shown) that are rigidly fixed to the downstream collar 20. All tether lines 200 and 201 are inextensible and, in this embodiment, are attached at points distributed roughly equidistant around the circumference of the O-ring 191. To retract and stow the filter, the operator pulls on the line 121 and the O-ring buckles into the configuration shown in Figure 11B due to the alternating

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attachments of the tether lines 200 and 201. The buckling of the O-ring 191 also helps to gather together the filter 7.

Although the invention has been described with reference to several preferred embodiments, it will be understood by one of ordinary skill in the art  
5 that various modifications can be made without departing from the spirit and the scope of the invention, as set forth in the claims hereinbelow.

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What is claimed is:

1. A catheter-filter set for use in a vas through which a biological fluid may flow, the vas having an interior wall, the fluid flow defining downstream and upstream directions, there being a risk of the presence of undesired particles in  
5 the fluid, the catheter-filter set comprising:
  - a. a tubular member, having a lumen disposed along its length and an insertion end for insertion into the vas, the lumen defining a longitudinal axis and a radial direction perpendicular thereto;
  - b. a filter, coupled to the tubular member and having a circumference,  
10 for trapping undesired particles; and
  - c. a resilient member, having compliance in the radial direction, disposed circumferentially about the filter and, when deployed in the vas, forming a seal against the interior wall.
2. A catheter-filter set according to claim 1, wherein the resilient member is  
15 an O-ring.
3. A catheter-filter set according to claim 1, wherein the resilient member is a sleeve.
4. A catheter-filter set according to claim 1, wherein the resilient member is a balloon having an interior for receiving an inflation fluid and a shape so that  
20 when the balloon is inflated there is provided a passageway permitting fluid flow through the filter.
5. A catheter-filter set according to claim 4, further comprising an elastic member coupled to the balloon and the tubular member for causing the balloon to be radially confined when not deployed.
- 25 6. A catheter-filter set according to claim 4, wherein the balloon is toroidal and its interior has a cross-section.
7. A catheter-filter set according to claim 6, wherein the resilient balloon has anisotropic elasticity so that during inflation its interior cross-section expands relatively less than its radial extent.
- 30 8. A catheter filter set according to claim 1, such that the filter has a stowed position where the filter is radially confined and disposed in the lumen so that

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the catheter-filter set may be inserted into and removed from the vas, and a deployed position, where the filter is radially expanded.

9. A catheter-filter set for use in a vas through which a biological fluid may flow, the vas having an interior wall, the fluid flow defining downstream and upstream directions, there being a risk of the presence of undesired particles in the fluid, the catheter-filter set comprising:
- a. a tubular member, having a first lumen disposed along its length, an insertion end for insertion into and a retraction end for retraction out of the vas, the lumen defining a longitudinal axis and a radial direction perpendicular thereto;
  - b. a filter, coupled to the tubular member proximal to the insertion end, wherein the filter has a stowed position wherein the filter is radially confined so that the catheter-filter set may be inserted into and removed from the vas, and a deployed position, wherein the filter is radially expanded; and
  - c. a non-inflatable actuator, coupled to the filter, for causing the filter to move from the stowed position to the deployed position; wherein, absent operation of the actuator, the filter is biased to be in the stowed position.
10. A catheter-filter set according to claim 9, further comprising:
- d. a vas conditions-modifying element, associated with the tubular member and located upstream from the filter.
11. A catheter-filter set according to claim 9 wherein element (d) is an angioplasty balloon.
12. A catheter-filter set according to claim 9, wherein the tubular member has a second lumen, the second lumen having an inlet upstream from the vas conditions-modifying element and an outlet downstream from the filter, permitting unimpeded, downstream fluid flow to bypass the filter.
13. A catheter-filter set according to claim 12, wherein the second lumen has a diameter of from approximately 1 mm to approximately 2 mm.
14. A catheter-filter set according to claim 9, further comprising:

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- d. a plurality of resilient ribs, each rib having a first end coupled to the tubular member, each rib also coupled to the filter, the ribs having a stowed condition in which they are parallel to the longitudinal axis and having a deployed condition in which at least a portion of each  
5 rib is disposed radially outward from the tubular member.
- 15. A catheter-filter set according to claim 14, wherein the filter, in the deployed position, has a maximum radial extent and each rib, in the deployed condition, radially extends a distance less than the maximum radial extent of the filter.
- 10 16. A catheter-filter set according to claim 14, wherein each rib has a second end slidably mounted on the tubular member and coupled to the actuator.
- 17. A catheter-filter set according to claim 16, wherein each rib is coupled to a collar slidably mounted on the tubular member.
- 18. A catheter-filter set according to claim 14, further comprising:  
15 e. a vas conditions-modifying element, associated with the tubular member and located upstream from the filter.
- 19. A catheter-filter set according to claim 18 wherein element (e) is an angioplasty balloon.
- 20. A catheter-filter set according to claim 18, wherein the tubular member has  
20 a second lumen, the second lumen having an inlet upstream from the vas conditions-modifying element and an outlet downstream from the filter, permitting unimpeded, downstream fluid flow to bypass the filter.
- 21. A catheter-filter set according to claim 20, wherein the second lumen has a diameter of from approximately 1 mm to approximately 2 mm.
- 25 22. A catheter-filter set according to claim 9, further comprising:
  - d. a resilient member, having compliance in the radial direction, disposed circumferentially about the filter and, when deployed in  
the vas, forming a seal against the interior wall.
- 23. A catheter-filter set according to claim 22, further comprising:  
30 e. a plurality of resilient ribs, each rib having a first end coupled to the tubular member, each rib also coupled to the filter, the ribs having a

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stowed condition in which they are parallel to the longitudinal axis and having a deployed condition in which at least a portion of each rib is disposed radially outward from the tubular member.

24. A catheter-filter set according to claim 23, wherein the filter, in the  
5 deployed position, has a maximum radial extent and each rib, in the deployed condition, radially extends a distance less than the maximum radial extent of the filter.
25. A catheter-filter set according to claim 23, wherein each rib has a second end slidably mounted on the tubular member and coupled to the actuator.
- 10 26. A catheter-filter set according to claim 25, wherein each rib is coupled to a collar slidably mounted on the tubular member.
27. A catheter-filter set according to claim 23, further comprising:  
f. a vas conditions-modifying element, associated with the tubular member and located upstream from the filter.
- 15 28. A catheter-filter set according to claim 27 wherein element (f) is an angioplasty balloon.
29. A catheter-filter set according to claim 23, wherein the tubular member has a second lumen, the second lumen having an inlet upstream from the vas conditions-modifying element and an outlet downstream from the filter,  
20 permitting unimpeded, downstream fluid flow to bypass the filter.
30. A catheter-filter set according to claim 29, wherein the second lumen has a diameter of from approximately 1 mm to approximately 2 mm.
31. A catheter-filter set according to claim 22, wherein the resilient member is an O-ring.
- 25 32. A catheter-filter set according to claim 22, wherein the resilient member is a sleeve.
33. A catheter-filter set according to claim 22, wherein the resilient member is a resilient balloon having an interior for receiving an inflation fluid and a shape so that when the resilient balloon is inflated there is provided a passageway  
30 permitting fluid flow through the filter.



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34. A catheter-filter set according to claim 33, wherein the resilient balloon is toroidal and its interior has a cross-section.

35. A catheter-filter set according to claim 34, wherein the resilient balloon has anisotropic elasticity so that during inflation its interior cross-section expands

5 relatively less than its radial extent.

36. A catheter-filter set for use in a vas through which a biological fluid may flow, the vas having an interior wall, the fluid flow defining downstream and upstream directions, there being a risk of the presence of undesired particles in the fluid, the catheter-filter set comprising:

- 10       a. a tubular member, having a lumen disposed along its length, an insertion end for insertion into and a retraction end for retraction out of the vas, the lumen defining a longitudinal axis and a radial direction perpendicular thereto; and
- b. a filter, coupled to the tubular member proximal to the insertion
- 15 end, wherein the filter has a stowed position wherein the filter is radially confined and disposed in the lumen so that the catheter-filter set may be inserted into and removed from the vas, and a deployed position, wherein the filter is radially expanded.

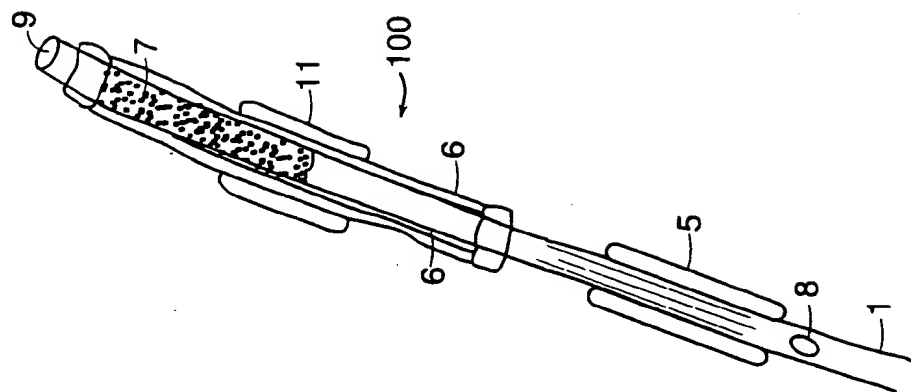


FIG. 1B

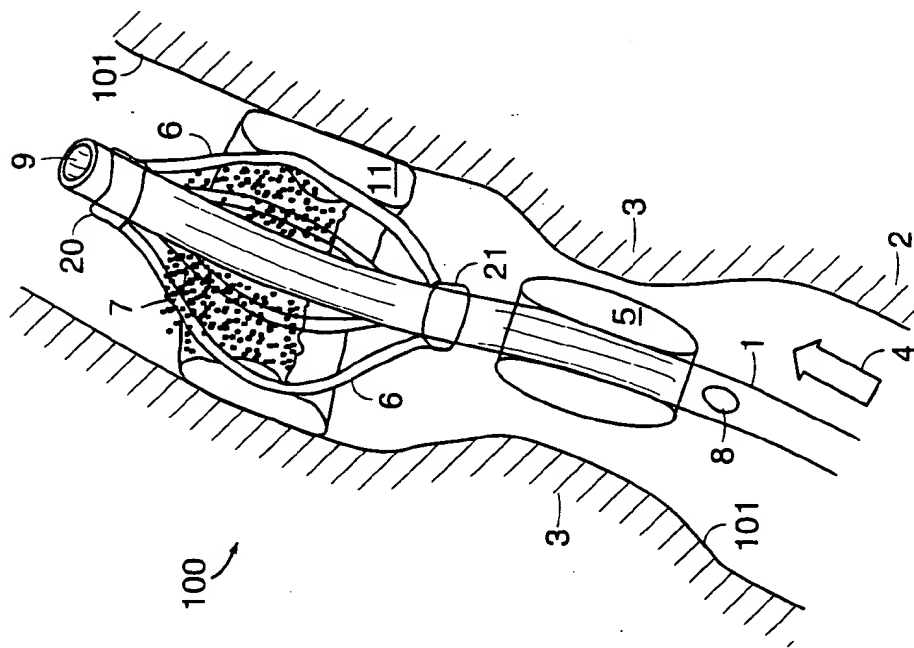


FIG. 1A

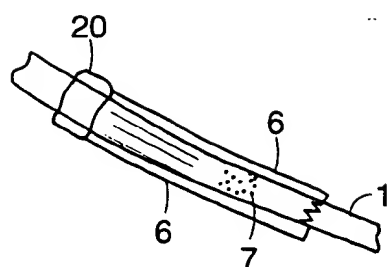


FIG. 2A

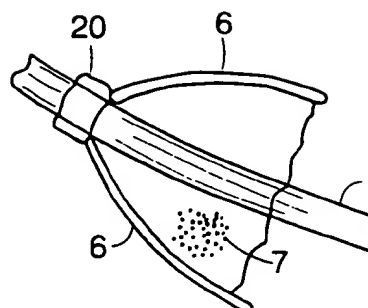


FIG. 2B

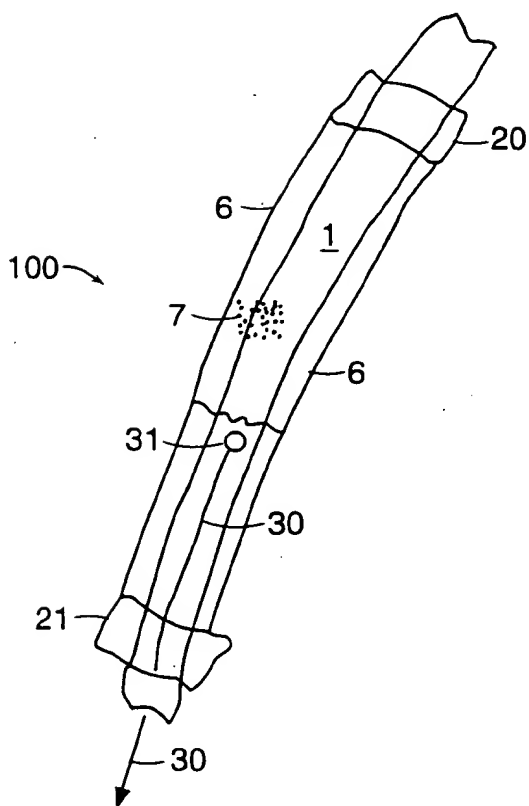


FIG. 3A

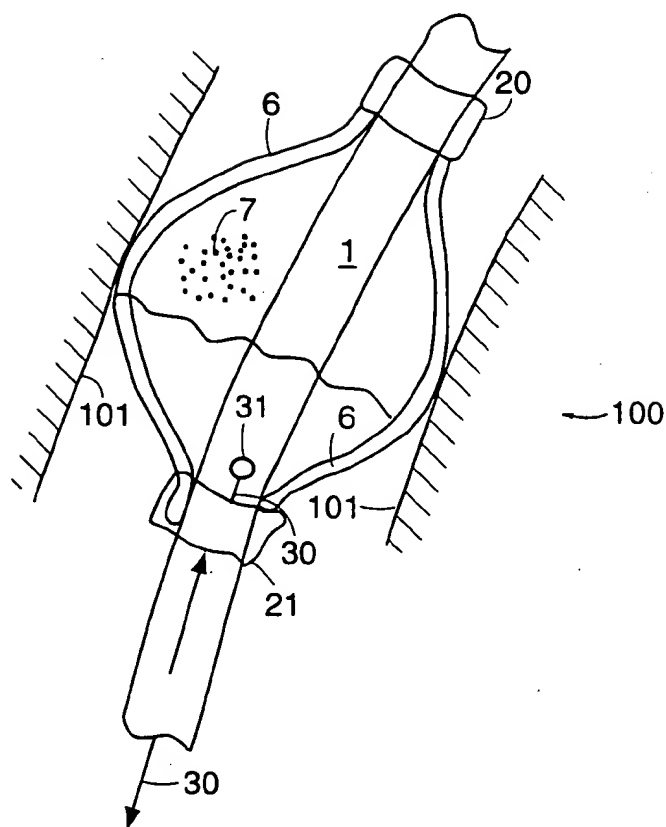


FIG. 3B

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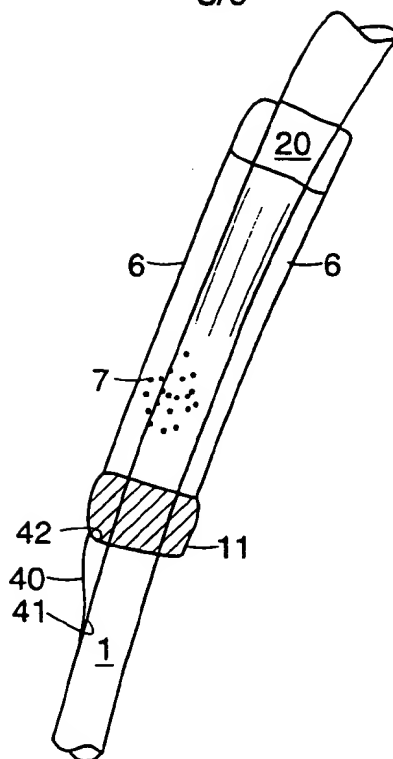


FIG. 4A

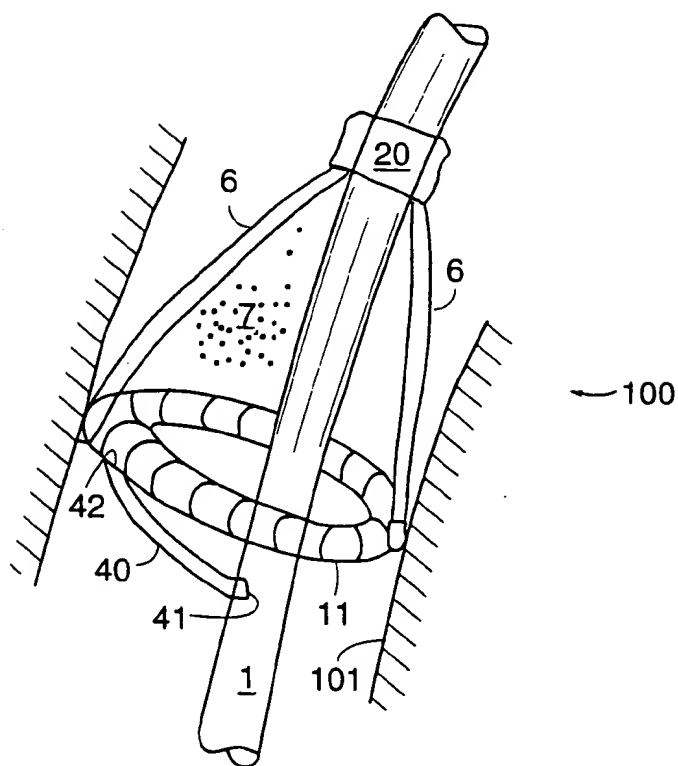


FIG. 4B

SUBSTITUTE SHEET (RULE 26)

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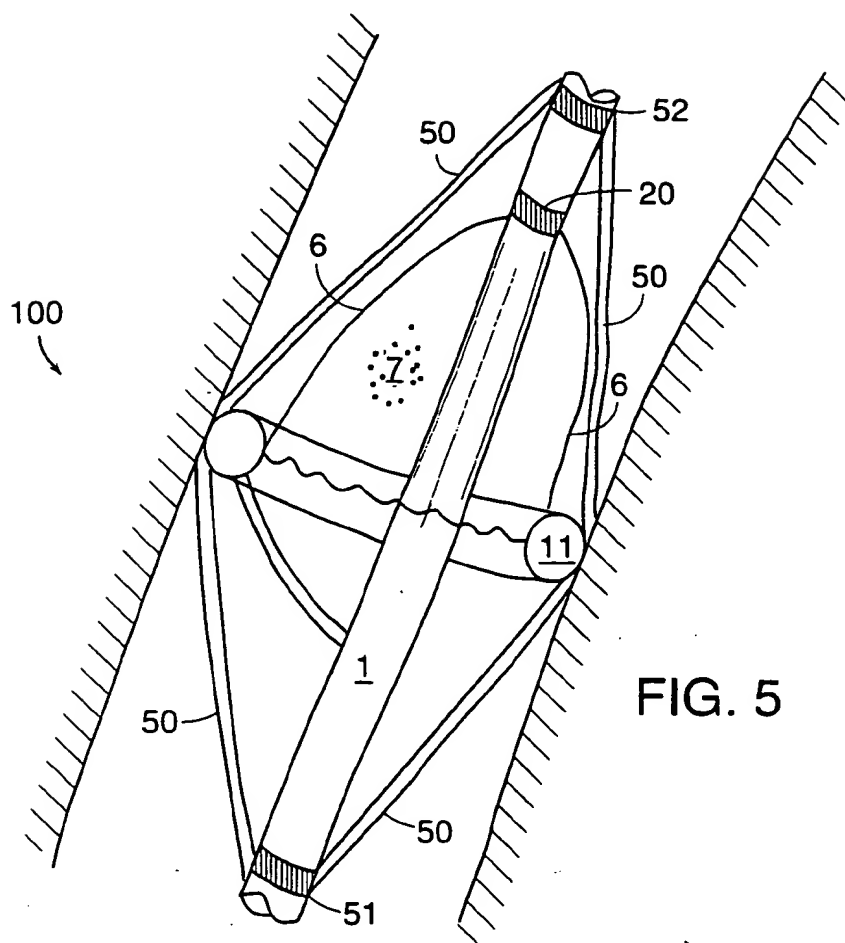


FIG. 5

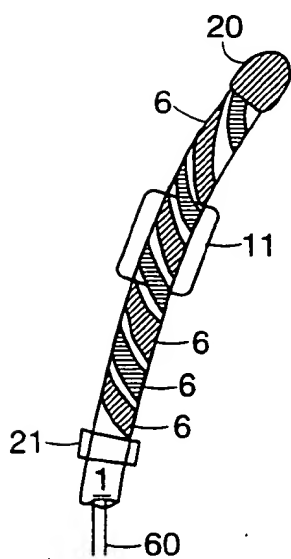


FIG. 6A

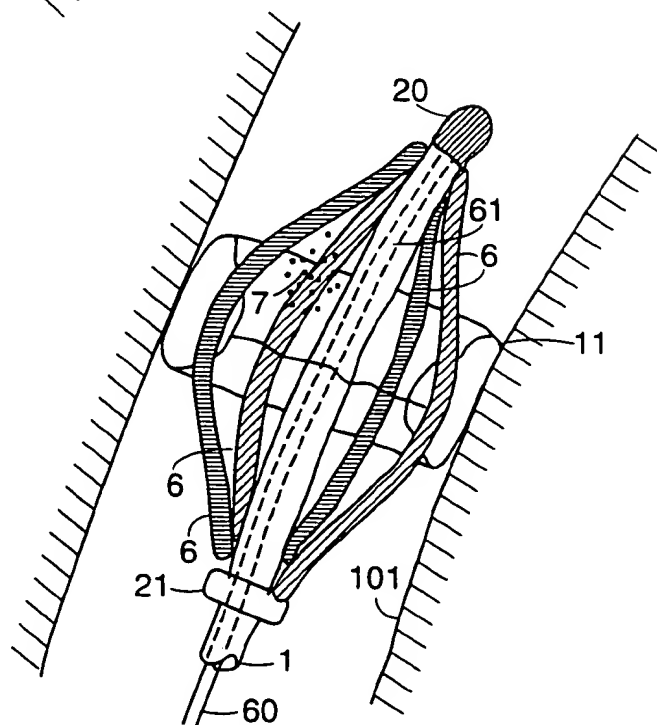


FIG. 6B

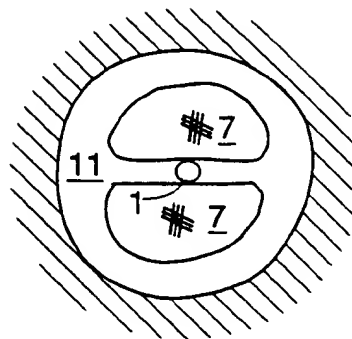


FIG. 7A

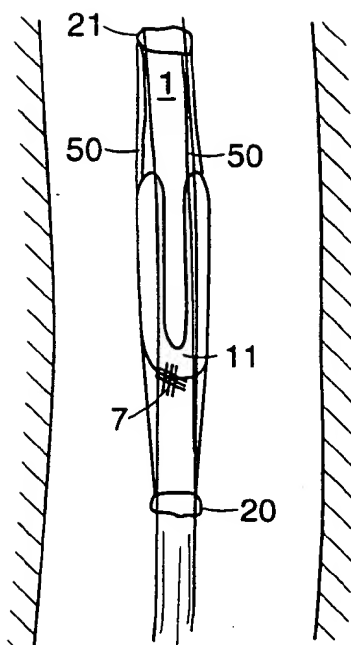


FIG. 7B

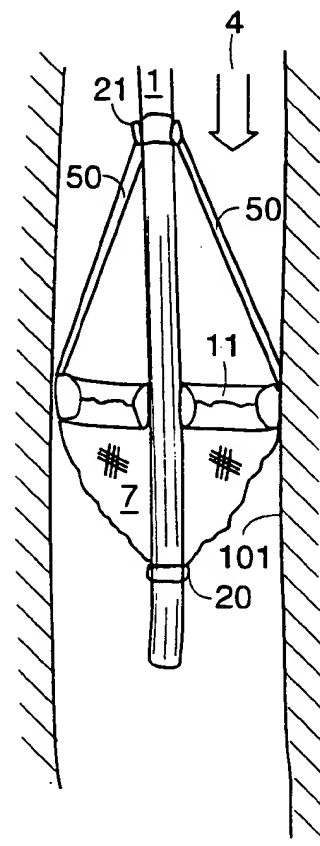


FIG. 7C

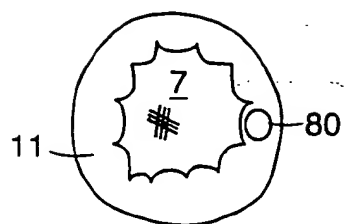


FIG. 8A

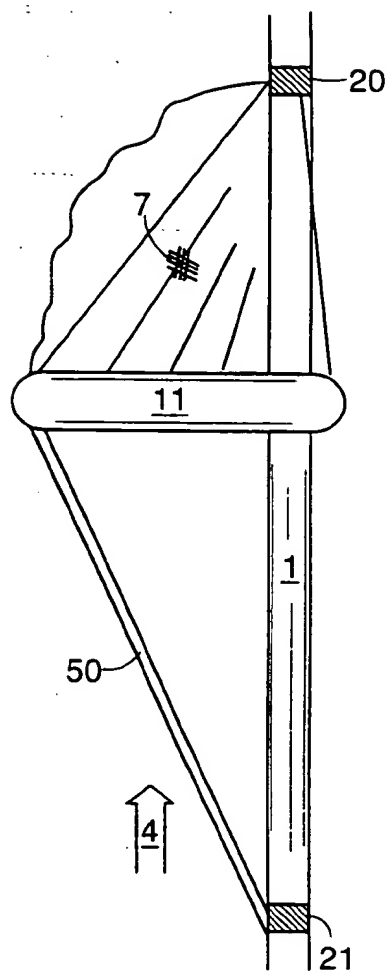


FIG. 8B

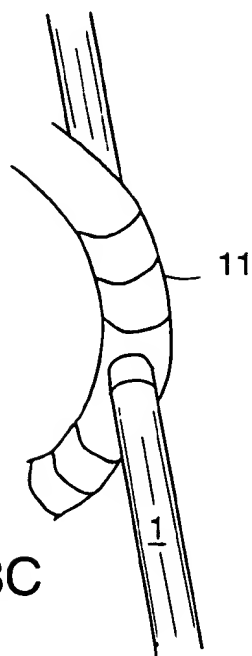


FIG. 8C

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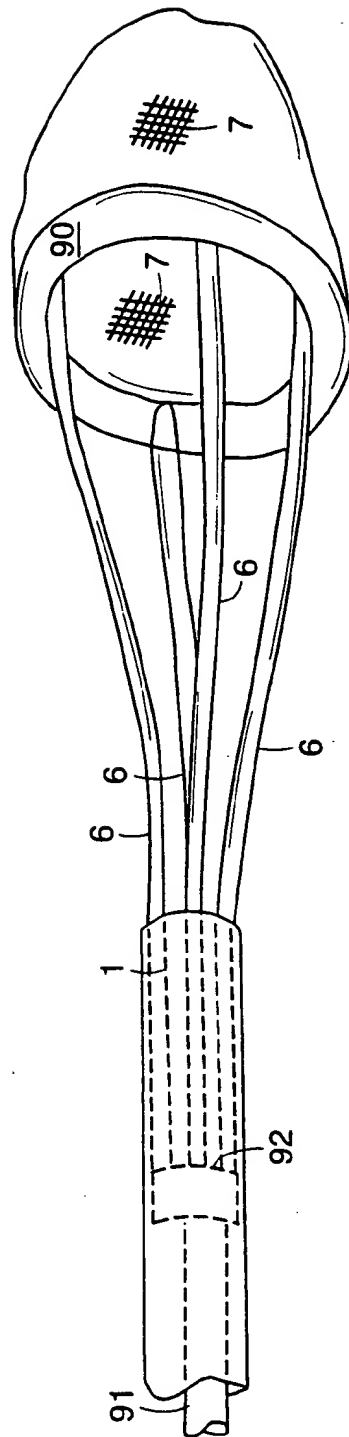


FIG. 9



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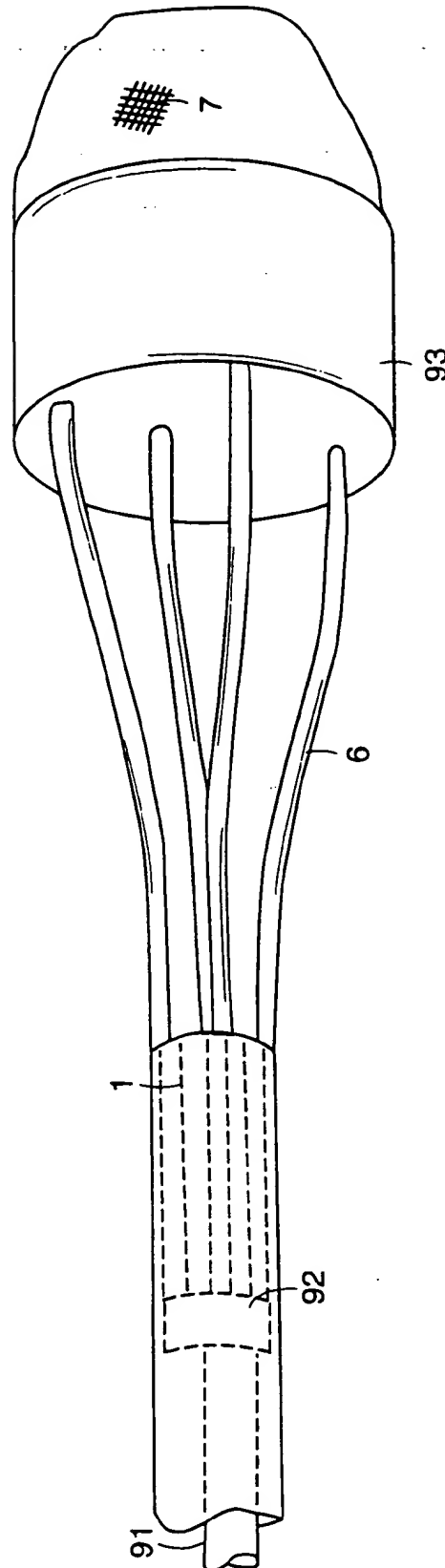


FIG. 10

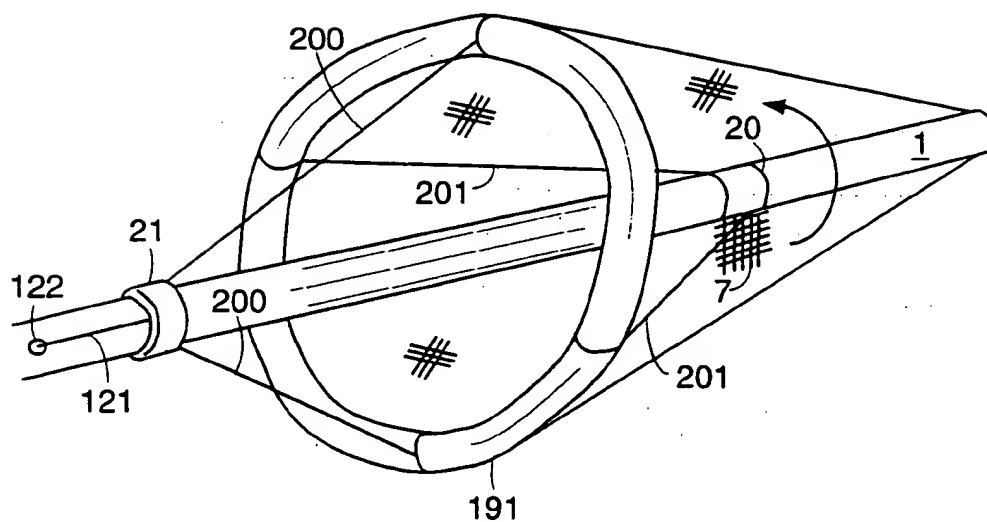


FIG. 11A

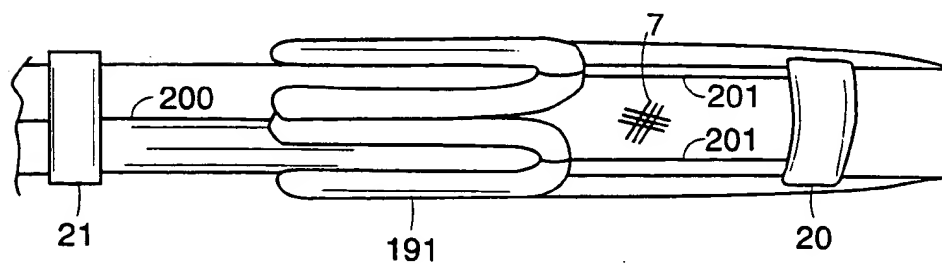


FIG. 11B

# INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 98/10220

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A61F2/01 A61M29/02

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95 05209 A (TECH. DEV. CENTER) 23 February 1995	1-4, 6-8, 36
Y	see page 13, line 29 - page 15, line 11 see page 7, line 6 - line 10; figures 1, 13-15	5, 9-35
Y	US 4 723 549 A (WHOLEY ET AL.) 9 February 1988 cited in the application see column 3, line 2 - line 66; figures 1-6	5, 9-35

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

21 August 1998

Date of mailing of the international search report

02/09/1998

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# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/10220

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>DATABASE WPI  Week 8122 8 July 1981  Derwent Publications Ltd., London, GB;  AN 78-70163A  XP002075206  &amp; SU 764 684 A (CHELY MED. INST.)  see abstract; figures 1-5</p>	1-3, 9, 36
X A	<p>US 5 053 008 A (BAJAJ) 1 October 1991  see column 7, line 55 - column 8, line 47;  figures 1-4</p>	1, 36 3, 7, 32, 35
A	<p>US 5 470 314 A (WALINSKY PAUL) 28 November  1995  see column 7, line 13 - line 18</p>	7, 35

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/10220

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9505209 A	23-02-1995	AU 7567394 A	14-03-1995
US 4723549 A	09-02-1988	NONE	
US 5053008 A	01-10-1991	NONE	
US 5470314 A	28-11-1995	NONE	

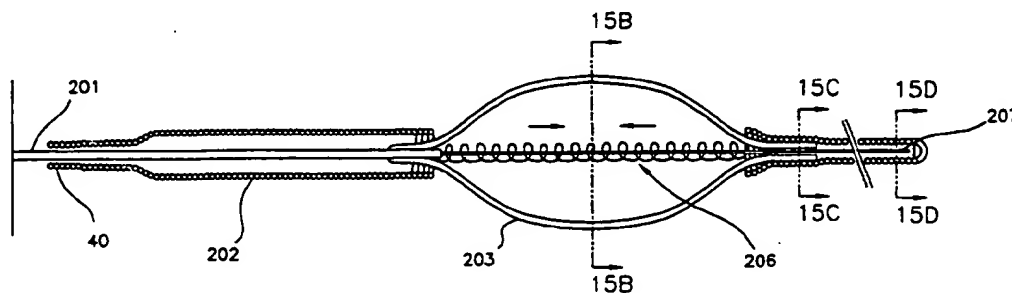




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>6</sup> :</b> <b>A61M 29/00</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 98/50103</b> <b>(43) International Publication Date:</b> 12 November 1998 (12.11.98)
<b>(21) International Application Number:</b> PCT/US98/08920 <b>(22) International Filing Date:</b> 1 May 1998 (01.05.98)  <b>(30) Priority Data:</b> 08/852,867      8 May 1997 (08.05.97)      US  <b>(71) Applicant:</b> EMBOL-X, INC. [US/US]; 3110 Coronado Drive, Santa Clara, CA 95054-3205 (US).  <b>(72) Inventors:</b> TSUGITA, Ross, S.; 1653 Gretel Lane, Mountain View, CA 94040 (US). MAAHS, Tracy, D.; 312 Sequoia Avenue, Redwood City, CA 94061 (US). JANG, Yue-Teh; 43659 Skye Road, Fremont, CA 94539 (US).  <b>(74) Agents:</b> KAPPOS, John, C. et al.; Lyon & Lyon LLP, Suite 4700, 633 West Fifth Street, Los Angeles, CA 90071-2066 (US).		<b>(81) Designated States:</b> AU, CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.</i>

**(54) Title:** PERCUTANEOUS CATHETER AND GUIDEWIRE HAVING FILTER AND MEDICAL DEVICE DEPLOYMENT CAPABILITIES

**(57) Abstract**

An apparatus and method for treating stenosed blood vessels is provided, more particularly a percutaneous catheter (10) including a filter (30) for capturing loose embolic material used to deliver a stent (20) preferably within the ascending aorta, the aortic arch, or the carotid arteries. The catheter (10) includes an expandable stent (20) deployed on an inflatable balloon (16), or alternatively a self-expanding stent. A filter (30) assembly is provided either directly on the catheter (10), or in a separate sheath (32), or on a guidewire (40). The filter assembly (30) comprises an expansion frame (52) having filter mesh (60) attached to it disposed on a guidewire (40) inserted through the catheter (10), or sheath (32), or alternatively attached directly on a distal region of the catheter (10). The expansion frame (52) comprises a structure which is activated from a contracted condition into an enlarged condition in a blood vessel, thereby traversing the vessel with the filter mesh (60). The expansion frame (52) includes biased struts, a mechanically operated frame, and/or a fluid operated frame. The catheter (10) is percutaneously introduced into a blood vessel and directed to a target region. The stent (20) is localized across the region. The filter assembly (30) is opened, and the stent (20) is deployed substantially permanently engaging the walls of the blood vessel, thereby opening the stenosed region and/or containing aortic plaque.

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## DESCRIPTION

### PERCUTANEOUS CATHETER AND GUIDEWIRE HAVING FILTER AND MEDICAL DEVICE DEPLOYMENT CAPABILITIES

5

## FIELD OF THE INVENTION

The present invention relates generally to treating plaque deposits and occlusions within major blood vessels, more particularly to an apparatus and method for preventing detachment of mobile aortic plaque within the ascending aorta, the aortic arch, or the carotid arteries, and to an apparatus and method for providing a stent and a filter in a percutaneous catheter for treating occlusions within the carotid arteries.

15

## BACKGROUND

Several procedures are now used to open stenosed or occluded blood vessels in a patient caused by the deposit of plaque or other material on the walls of the blood vessels. Angioplasty, for example, is a widely known procedure wherein an inflatable balloon is introduced into the occluded region. The balloon is inflated, dilating the occlusion, and thereby increasing intraluminal diameter. Plaque material may be inadvertently dislodged during angioplasty, and this material is then free to travel downstream, possibly lodging within another portion of the blood vessel or possibly reaching a vital organ, causing damage to the patient.

25 In another procedure, stenosis within arteries and other blood vessels is treated by permanently or temporarily introducing a stent into the stenosed region to open the lumen of the vessel. The stent typically comprises a substantially cylindrical tube or mesh sleeve made from such materials as stainless steel or nitinol. The design of the material permits the diameter of the stent to be radially expanded, while still providing sufficient rigidity such that the stent maintains its shape once it has been enlarged to a desired size.

30

Generally, a stent having a length longer than the target region is selected and is disposed on a catheter prior to use. The catheter typically has a flexible balloon, near its distal end, designed to inflate to a desired size when subjected to internal pressure. The stent is mounted to the catheter and compressed over the  
5 balloon, typically by hand, to assure that the stent does not move as it passes through the blood vessel to the desired location within the patient. Alternatively, self-expanding stents may also be used.

The stent is typically introduced into the desired blood vessel using known percutaneous methods. The catheter, having the stent securely crimped thereon, is  
10 directed to the region of the blood vessel being treated. The catheter is positioned such that the stent is centered across the stenosed region. The balloon is inflated, typically by introducing gas or fluid such as saline solution, through a lumen in the catheter communicating with the balloon. Balloon inflation causes the stent to expand radially, thereby engaging the stenosed material. As the stent expands, the  
15 material is forced outward, dilating the lumen of the blood vessel.

Due to substantial rigidity of the stent material, the stent retains its expanded shape, providing an open passage for blood flow. The balloon is then deflated and the catheter withdrawn.

Because the stent is often constructed from a mesh material, the stent  
20 typically compresses longitudinally as it expands radially. Stenotic material trapped between the stent and the vessel wall may extend into the openings in the mesh and may be sheared off by this longitudinal compression to create embolic debris free. When this material travels downstream, it can cause serious complications. For example loose embolic material released within the ascending aorta,  
25 the aortic arch, or the carotid arteries may travel downstream to the brain, possibly causing stroke, which can lead to permanent injuries or even death of the patient.

Thus, there is a need for an apparatus and method for delivering a stent into an arterial occlusion which substantially reduces the risk of embolic material escaping to the vessel and causing a blockage at a downstream location. There is  
30 also an apparatus and method for substantially preventing detachment of plaque deposited on the walls of the ascending aorta, the aortic arch, the descending aorta,

and the carotid arteries. In addition, there is a need for an apparatus and method to substantially contain loose embolic material within the aorta and the carotid arteries during an interventional procedure, preventing it from reaching the brain.

### SUMMARY OF THE INVENTION

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The present invention provides an apparatus and method for preventing embolic material from escaping a site of intervention within the aorta, the carotid arteries, and other arteries generally, thereafter causing damage to vital organs, such as the brain. More particularly, the present invention involves an apparatus and method for introducing a stent into a region of a major blood vessel within the human body having plaque deposits, such as the ascending aorta, the descending aorta, aortic arch, common carotid artery, external and internal carotid arteries, brachiocephalic trunk, middle cerebral artery, anterior cerebral artery, posterior cerebral artery, vertebral artery, basilar artery, subclavian artery, brachial artery, axillary artery, iliac artery, renal artery, femoral artery, popliteal artery, celiac artery, superior mesenteric artery, inferior mesenteric artery, anterior tibial artery, and posterior tibial artery, thereby opening occlusions and/or preventing embolic material from breaking free within the blood vessel.

10 In a first embodiment, the invention includes a guidewire having an expandable filter attached to it, and a stent catheter. The catheter has an inflatable balloon mounted on or near its distal end, and an inflation lumen extending through the catheter between a proximal region of the catheter and the balloon. A stent is provided on the outer surface of the catheter, substantially engaging the balloon. Generally, the stent comprises an expandable substantially rigid tube, sheet, wire or spring, but preferably a cylindrical mesh sleeve. See Palmaz, U.S. Patent No. 4,733,665, incorporated herein by reference.

25 Alternatively, the stent may be a self-expanding sleeve, preferably from nitinol. In this case, the stent catheter does not require an inflatable balloon. Instead the stent is compressed over the catheter and a sheath or outer catheter is directed over the stent to hold it in the compressed condition until time of

30

deployment.

The guidewire has a filter assembly attached at or near its distal end, which includes an expansion frame which is adapted to open from a contracted condition to an enlarged condition. Filter material, typically a fine mesh, is attached to the expansion frame to filter undesirable embolic material from blood.

The guidewire with the expansion frame in its contracted condition is provided through a sheath or cannula, or preferably is included directly in the stent catheter. The catheter typically has a second lumen extending from its proximal region to its distal end into which the guidewire is introduced. The filter assembly on the distal end of the guidewire is then available to be extended beyond the distal end of the catheter for use during stent delivery.

The device is typically used to introduce a stent into a stenosed or occluded region of a patient, preferably within the carotid arteries. The catheter is introduced percutaneously into a blood vessel and is directed through the blood vessel to the desired region. If the filter device is provided in a separate sheath, the sheath is percutaneously inserted into the blood vessel downstream of the region being treated, and is fixed in position.

The filter assembly is introduced into the blood vessel, and the expansion frame is opened to its enlarged condition, extending the filter mesh substantially across the blood vessel until the filter mesh substantially engages the walls of the vessel.

The catheter is inserted through the region being treated until the stent is centered across the plaque deposited on the walls of the blood vessel. Fluid, preferably saline solution, is introduced through the inflation lumen, inflating the balloon, and expanding the stent radially outwardly to engage the plaque. The stent pushes the plaque away from the region, dilating the vessel. The balloon is deflated, and the catheter is withdrawn from the region and out of the patient. The stent remains substantially permanently in place, opening the vessel and trapping the plaque beneath the stent.

When the stenosed region is opened, embolic material may break loose from the wall of the vessel, but will encounter the filter mesh and be captured

therein, rather than traveling on to lodge itself elsewhere in the body. After the stent is delivered, the expansion frame is closed, containing any material captured in the filter mesh. The filter assembly is withdrawn back into the sheath or the catheter itself, which is then removed from the body.

5        If a self-expanding stent is used, the stent catheter with the compressed stent thereon is inserted into a sheath, which restrains the stent in a compressed condition. The catheter is introduced into the patient's blood vessel and directed to the target region. Once the stent is localized across the stenosed region and the filter assembly is in position, the sheath is drawn proximally in relation to the  
10       catheter. This exposes the stent, which expands to engage the wall of the blood vessel, opening the lumen. The filter assembly is then closed and the catheter withdrawn from the patient.

         The filter assembly has a number of preferred forms. For example, the expansion frame may comprise a plurality of struts or arms attached to and  
15       extending distally from the distal end of the guidewire. The struts are connected to each other at each end and have an intermediate region which is biased to expand radially. Filter mesh is attached typically between the intermediate region and the distal ends of the struts, thereby defining a substantially hemispherical or conical shaped filter assembly.

20       To allow the filter assembly to be inserted into the lumen of the sheath, the intermediate region of the expansion frame is compressed. When the filter assembly is ready to be introduced into a blood vessel, the guidewire is pushed distally. The expansion frame exits the lumen, and the struts automatically open radially. This expands the filter mesh to substantially traverse the vessel. After  
25       the stent is delivered, the guidewire is pulled proximally to withdraw the filter assembly. The struts contact the wall of the filter lumen, forcing them to compress, closing the frame as the filter assembly is pulled into the sheath.

         In another embodiment, the expansion frame includes a plurality of struts attached to the distal end of the sheath. The struts extend distally from the sheath  
30       and attach to the distal end of the guidewire which is exposed beyond the sheath. At an intermediate region, the struts are notched or otherwise biased to fold out

radially. Filter mesh is attached to the struts between the intermediate region and the distal end of the guidewire.

The filter assembly is directed into position in the blood vessel, either exposed on the end of the sheath or preferably within a second sheath which is withdrawn partially to expose the filter assembly. With the sheath fixed, the guidewire is pulled proximally. This compresses the struts, causing them to bend or buckle at the intermediate region and move radially outwardly, expanding the filter mesh across the blood vessel. After use, the guidewire is pushed distally, pulling the struts back down and closing the filter mesh.

In an alternative to this embodiment, the struts attached to the distal end of the sheath and to the distal end of the guidewire are biased to expand radially at an intermediate region. The filter mesh is attached to the struts between the intermediate region and the distal end of the guidewire. Prior to introduction into a patient, the guidewire is rotated torsionally in relation to the sheath, twisting the struts axially around the guidewire and compressing the filter mesh. Once in position in the blood vessel, the guidewire is rotated in the opposite direction, unwinding the struts. The struts expand radially, opening the filter mesh. After use, the guidewire is rotated once again, twisting the struts and closing the filter mesh for removal.

In yet another embodiment, the filter assembly comprises a plurality of substantially cylindrical compressible sponge-like devices attached in series to the guidewire. The devices have an uncompressed diameter substantially the same as the open regions of the blood vessel. They are sufficiently porous to allow blood to pass freely through them but to entrap undesirable substantially larger particles, such as loose embolic material.

The devices are compressed into the lumen of the sheath prior to use. Once in position, they are introduced into the blood vessel by pushing the guidewire distally. The devices enter the vessel and expand to their uncompressed size, substantially engaging the walls of the blood vessel. After use, the guidewire is pulled proximally, forcing the devices against the distal end of the sheath and compressing them back into the lumen.

In a second embodiment, a stent catheter and filter assembly are also provided. Unlike the previous embodiments, the filter assembly is not primarily mechanically operated, but is instead, generally fluid operated. Typically, the stent catheter includes a second balloon on or near the distal end of the catheter. A  
5 second inflation lumen extends through the catheter from the proximal region of the catheter to the balloon. The balloon is part of the expansion frame or alternatively merely activates the expansion frame, opening the filter assembly to the enlarged condition for use and closing it after being used.

In one form, the balloon has an annular shape. Filter mesh is attached  
10 around the perimeter of the balloon, creating a conical or hemispherical-shaped filter assembly. A flexible lumen extends between the balloon and the inflation lumen within the catheter. Optionally, retaining wires are connected symmetrically between the balloon and the catheter, thereby holding the balloon substantially in a desired relationship to the catheter.

15 When deflated, the balloon substantially engages the periphery of the catheter, holding the filter mesh closed and allowing the catheter to be directed to the desired location. Once the catheter is in position, the balloon is inflated. The balloon expands radially until it engages the walls of the blood vessel, the filter mesh thereby substantially traversing the vessel. After use, the balloon is deflated  
20 until it once again engages the perimeter of the catheter, thereby trapping any embolic material between the filter mesh and the outer wall of the catheter.

Alternatively, the balloon of this embodiment may be provided on the catheter proximal of the stent for retrograde use. In this case, the filter mesh is extended between the balloon and the outer surface of the catheter, instead of  
25 having a closed end.

In a third embodiment of the present invention, a method is provided in which a stent catheter is used to prevent the detachment of mobile aortic deposits within the ascending aorta, the aortic arch or the carotid arteries, either with or without an expandable filter assembly. A stent catheter, as previously described,  
30 is provided having an inflatable balloon and a stent thereon, or alternatively a self-expanding stent and a retaining sheath. The catheter is percutaneously introduced

into a blood vessel and is directed to a region having mobile aortic plaque deposits, preferably a portion of the ascending aorta or the aortic arch.

The stent is positioned across the desired region, and the balloon is inflated. This expands the stent to engage the plaque deposits and the walls of the blood vessel, thereby trapping the plaque deposits. The balloon is deflated, and the catheter is removed from the blood vessel. Alternatively if a self-expanding stent is used, the sheath is partially withdrawn proximally, and the stent is exposed, allowing it to expand. The stent substantially retains its expanded configuration, thereby containing the plaque beneath the stent and preventing the plaque from subsequently detaching from the region and traveling downstream.

Optionally, a filter device similar to those already described may be introduced at a location downstream of the treated region. The filter device may be provided in a sheath which is inserted percutaneously into the blood vessel. Preferably, however, a filter device is attached to the stent catheter at a location proximal to the stent. Instead of attaching the filter assembly to a guidewire, it is connected directly to the outer surface of the catheter proximal to the stent. A sheath or cannula is typically provided over the catheter to cover the filter assembly.

Once the catheter is in position within the vessel, the sheath is withdrawn proximally, the filter assembly is exposed and is expanded to its enlarged condition. In a preferred form, the expansion frame includes biased struts similar to the those described above, such that when the filter assembly is exposed, the struts automatically expand radially, and filter mesh attached to the struts is opened. After the stent is deployed, the sheath is moved proximally, covering the expansion frame and compressing the struts back into the contracted condition. The catheter and sheath are then withdrawn from the patient.

Thus, an object of the present invention is to provide an apparatus and method for substantially preventing mobile aortic plaque deposited within the ascending aorta, the aortic arch, or the carotid arteries from detaching and traveling to undesired regions of the body.

Another object is to provide an apparatus and method for treating stenosed



or occluded regions within the carotid arteries.

An additional object is to provide an apparatus and method for introducing a stent to treat a stenosed or occluded region of the carotid arteries which substantially captures any embolic material released during the procedure.

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### BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the invention, and to show how it may be carried into effect, reference will be made, by way of example, to the accompanying drawings, in which:

10        Fig. 1 is a longitudinal view of an embodiment being inserted into a blood vessel, namely a stent catheter in a stenosed region and a filter device downstream of the region.

Fig. 2 is a longitudinal view of another embodiment, showing the filter device included in the stent catheter.

15        Fig. 3 is a longitudinal view of an embodiment of the filter assembly in its enlarged condition within a blood vessel.

Figs. 4A, 4B and 4C show a longitudinal view of an embodiment of the filter assembly in a contracted condition, a partially expanded condition, and an enlarged condition respectively within a blood vessel.

20        Figs. 5A, 5B and 5C show a longitudinal view of another embodiment of the filter device in a contracted condition, a partially opened condition, and an enlarged condition across a blood vessel respectively.

25        Figs. 6A and 6B are longitudinal views, showing the orientation of the filter mesh in an antegrade approach to a stenosed region and in a retrograde approach respectively.

Fig. 7 is a longitudinal view of another embodiment of the filter assembly.

Figs. 8A and 8B are longitudinal views of another embodiment of the filter assembly, showing the filter mesh without gripping hairs and with gripping hairs respectively.

30        Fig. 9 is a longitudinal view of another embodiment of the filter assembly including sponge-like devices.

Fig. 10 is a longitudinal view of another embodiment, namely a filter assembly attached to the outer surface of a stent catheter.

Figs. 11A and 11B show a filter assembly attached to the outer surface of a stent catheter, with a sheath retaining the filter assembly in the contracted condition, and with the filter assembly in the enlarged condition respectively.

Figs. 12A and 12B are longitudinal views of another embodiment including an inflatable filter assembly, shown in a contracted condition and an enlarged condition respectively.

Fig. 13 is a longitudinal view of an inflatable filter assembly attached to the catheter proximal of the stent shown in an enlarged condition.

Figs. 14 depicts a longitudinal view of a stent deployment device having a distal filter disposed within a carotid artery.

Figs. 15 and 15A show detailed longitudinal views of a guidewire filter in accordance with the present invention.

Figs. 16, 16A, 16B, and 16C show longitudinal and cross-sectional views of an eggbeater filter in accordance with the present invention.

Figs. 17 and 17A show longitudinal views of a filter scroll in accordance with the present invention.

Figs. 18, 18A, and 18B show longitudinal views of a filter catheter in accordance with the present invention.

Fig. 19 shows an alternate construction for an eggbeater filter as disclosed herein.

Fig. 20 shows a longitudinal view of an imaging guidewire having an eggbeater filter and restraining sheath.

Fig. 21 shows human aortic anatomy and depicts several routes for deployment of an aortic filter upstream of the carotid arteries.

Fig. 22 depicts a longitudinal view of a generalized filter guidewire.

Figs. 23 and 23A depict longitudinal views of a compressible, expansible sheath disposed over a guidewire in accordance with the present disclosure.

### DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning to Fig. 1, a first embodiment of the present invention is shown, namely a stent catheter 10 and a filter device 30. The stent catheter 10 typically includes a catheter body 12, an inflatable balloon 16, and a stent 20. The catheter body 12 typically comprises a substantially flexible member having a proximal end (not shown) and a distal end 14. The balloon is mounted on a region at or near the distal end 14 of the catheter body 12. An inflation lumen 18 extends longitudinally from a region at or near the proximal end of the catheter body 12 to the balloon 16.

The stent 20 is introduced over the balloon 16, typically by manually compressing it onto the balloon 16. The stent 20 may comprise a tube, sheet, wire, mesh or spring, although preferably, it is a substantially cylindrical wire mesh sleeve, that is substantially rigid, yet expandable when subjected to radial pressure. Many known stent devices are appropriate for use with the present invention, such as those discussed elsewhere in this disclosure. Generally the stent is furnished from materials such as stainless steel or nitinol, with stainless steel being most preferred.

Alternatively, a self-expanding stent (not shown) may also be used, such as those disclosed in Regan, U.S. Patent No. 4,795,458, Harada et al., U.S. Patent No. 5,037,427, Harada, U.S. Patent No. 5,089,005, and Mori, U.S. Patent No. 5,466,242, the disclosures of which are incorporated herein by reference. Such stents are typically provided from nitinol or similar materials which are substantially resilient, yet compressible. When an expandable stent is used, the stent catheter does not generally include an inflatable balloon for the stent. Instead, the stent is compressed directly onto the catheter, and a sheath is placed over the stent to prevent it from expanding until deployed.

In addition to the catheter 10, the present invention typically includes a filter device 30. The filter device 30 generally comprises an introducer sheath 32, a guidewire 40, and an expandable filter assembly 50, although alternatively the guidewire 40 and the filter assembly 50 may be provided directly on the catheter 10 as will be described below (see Fig. 2). The sheath 32 has a proximal end 34

and a distal end 36, and generally includes a hemostatic seal 38 mounted on its proximal end 34. The guidewire 40, typically a flexible, substantially resilient wire, having a distal end 42 and a proximal end 44, is inserted into the proximal end 34 of the sheath 32 through a lumen 33. A hub or handle 46 is generally  
5 mounted on the proximal end 44 for controlling the guidewire 40.

Generally, attached on or near the distal end 42 of the guidewire 40 is an expandable filter assembly 50 which generally comprises an expansion frame 52 and filter mesh 60. The expansion frame 52 is generally adapted to open from a contracted condition while it is introduced through the lumen 33 of the sheath 32  
10 to an enlarged condition once it is exposed within a blood vessel 70, as will be discussed more particularly below. The filter mesh 60 is substantially permanently attached to the expansion frame 52.

The construction of the stent catheter 10 should already be familiar to those skilled in the art. The catheter body 12 is typically made from substantially  
15 flexible materials such as polyethylene, nylon, PVC, polyurethane, or silicone, although materials such as polyethylene and PVC are preferred. The balloon 16 for delivering the stent 20 is generally manufactured from a substantially flexible and resilient material, such as polyethylene, polyester, latex, silicone, or more preferably polyethylene and polyester. A variety of balloons for angioplasty or  
20 stenting procedures are available which have a range of known inflated lengths and diameters, allowing an appropriate balloon to be chosen specifically for the particular blood vessel being treated.

The sheath 32 for the filter device 30 generally comprises a conventional flexible sheath or cannula for introducing catheters or guidewires into the blood  
25 stream of a patient. Exemplary materials include polyethylene, nylon, PVC, or polyurethane with polyethylene and PVC being most preferred. The hemostatic seal 38 generally is an annular seal designed to prevent the escape of blood from the vessel through the sheath 32, and includes materials such as silicone, latex, or urethane, or more preferably silicone. The hemostatic seal 38 is substantially  
30 permanently adhered to the proximal end 34 of the sheath 32 using known surgically safe bonding materials.

The guidewire 40 is generally manufactured from conventional resilient wire such as stainless steel or nitinol, although stainless steel is preferred, having a conventional hub or handle 46 formed integral with attached to its proximal end 44.

5       Turning now to Fig. 3, the filter assembly 50 of the present invention is generally shown extending from the distal end 36 of a sheath or catheter 32 and in an enlarged condition within a blood vessel 70. The filter assembly 50 includes an expansion frame 52 comprising a plurality of struts, ribs or wires 54, each strut 54 having a substantially fixed proximal end 56 and a distal end 58, which may or  
10       may not be fixed. The proximal ends 56 are typically connected to the distal end 42 of the guidewire 40, or alternatively to the outer surface of a distal region (not shown in Fig. 3) of the guidewire 40, typically using conventional bonding methods, such as welding, soldering, or gluing. The distal ends 58 of the struts 54 are connected to the filter mesh 60, or alternatively to the distal end of the  
15       guidewire (not shown). The struts generally comprise substantially resilient materials such as stainless steel or nitinol, with stainless steel being preferred.

Generally, the filter mesh 60 comprises a fine mesh having an open region 64 substantially engaging the wall 72 of the blood vessel 70 and a closed region 62, shown here as the apex of a cone. An appropriate mesh is selected, having a  
20       pore size that permits blood to flow freely through the mesh, while capturing therein undesired particles of a targeted size. Appropriate filter materials are disclosed in co-pending applications Barbut et al., U.S. Application Serial No. 08/553,137, filed November 7, 1995, Barbut et al., U.S. Application Serial No. 08/580,223, filed December 28, 1995, Barbut et al., U.S. Application Serial No.  
25       08/584,759, filed January 9, 1996, Barbut et al., U.S. Application Serial No. 08/640,015, filed April 30, 1996, Barbut et al., U.S. Application Serial No. 08/645,762, filed May 14, 1996, and Maahs, U.S. Application Serial No. 08/842,727, filed April 16, 1997. The disclosure of these references and any others cited herein are expressly incorporated herein by reference. An exemplary  
30       embodiment of the mesh has a mesh area of 3-8 sq. in., a mesh thickness of 60-

200 $\mu$ m, a thread diameter of 30–100 $\mu$ m, and a pore size of 60–100 $\mu$ m.

Polyethylene meshes, such as Saati Tech and Tetko, Inc. meshes, provide acceptable filter materials, as they are available in sheet form and can be easily cut and formed into a desired shape. The mesh is formed into a desired filter shape and is sonic welded or adhesive bonded to the struts 54.

The present invention is then typically used to introduce a stent into a stenosed or occluded region of a patient, preferably for treating a region within the carotid arteries. Referring again to Figs. 1 and 2, the catheter 10 is first introduced into a blood vessel 70 using known percutaneous procedures, and then is directed through the blood vessel to the stenosed region of the target blood vessel. The catheter 10 is typically introduced in an upstream-to-downstream (antegrade) orientation as shown in Figs. 1 and 14, although the catheter may also be introduced in a downstream-to-upstream (retrograde) orientation as will be described below. In a preferred example, the catheter 10 is inserted into a femoral artery and directed using known methods to a carotid artery, as shown in Fig. 14, or alternatively is introduced through a lower region of a carotid artery and directed downstream to the stenosed location 74.

The sheath 32 is percutaneously introduced into the blood vessel 70 downstream of the stenosed region 74, and is deployed using conventional methods. The distal end 42 of the guidewire 40 is directed through the lumen 33 of the sheath 32 until the filter assembly 50 is introduced into the blood vessel 70 by pushing distally on the hub 46 on the guidewire 40. When the distal end 42 of the guidewire 40 enters the blood vessel 70, the expansion frame 52 is opened to its enlarged condition, extending substantially across the entire cross-section of the vessel 70. The filter mesh 60 attached to the frame 52 substantially engages the luminal walls 72 of the vessel 70, thereby capturing any undesirable loose material passing along the blood vessel 70 from the treated region 74.

The catheter 10 is inserted through the stenosed region 74 until the stent 20 is centered across the plaque or embolic material 76 deposited on the walls 72 of the blood vessel 70. If the region 74 is substantially blocked, it may be necessary to first open the region 74 using a balloon catheter prior to insertion of the stent

catheter (not shown in Fig. 3), as will be familiar to those skilled in the art. Once the stent 20 is in the desired position, fluid, saline, or radiographic contrast media, but preferably radiographic contrast media, is introduced through the inflation lumen 18 to inflate the balloon 16. As the balloon 16 expands, the pressure forces the stent 20 radially outwardly to engage the plaque 76. The plaque 76 is pushed away from the region 74, opening the vessel 70. The stent 20 covers the plaque 76, substantially permanently trapping it between the stent 20 and the wall 72 of the vessel 70. Once the balloon 16 is fully inflated, the stent 20 provides a cross-section similar to the clear region of the vessel 70. The balloon 16 is then deflated by withdrawing the fluid out of the inflation lumen 18 and the catheter 12 is withdrawn from the region 74 and out of the patient using conventional methods. The stent 20 remains in place, substantially permanently covering the plaque 76 in the treated region 74 and forming part of the lumen of the vessel 70.

As the stenosed region 74 is being opened, or possibly as the catheter 12 is being introduced through the region 74, plaque may break loose from the wall 72 of the vessel 70. Blood flow will carry the material downstream where it will encounter the filter mesh 60 and be captured therein. Once the catheter 12 is removed from the treated region 74, the expansion frame 52 for the filter mesh 60 is closed to the contracted position, containing any material captured therein. The filter assembly 50 is withdrawn into the lumen 33 of the sheath 32, and the filter device 30 is removed from the body.

In another embodiment, shown in Fig. 2, the guidewire 40 and the filter assembly 50 are included within the stent catheter 10, rather than being provided in a separate sheath, thus eliminating the need for a second percutaneous puncture into the patient. As already described, the catheter 12 is provided with an inflatable balloon 16 furnished near its distal end 14 and with a stent 20 compressed over the balloon 16. In addition to the inflation lumen 18, a second lumen 19 extends through the catheter 12 from a proximal region (not shown) to its distal end 14. A guidewire 40, having a filter assembly 50 on its distal end 42, is introduced through the lumen 19 until its distal end 42 reaches the distal end 14 of the catheter 12. As before, the filter assembly 50 comprises an expansion frame

52 and filter mesh 60, which remain within the lumen 19 of the catheter 12 until deployed.

As described above, the stent catheter 10 is percutaneously introduced and is directed through the blood vessels until it reaches the stenosed region 74 and the stent 20 is centered across the plaque 76. The guidewire 40 is pushed distally, introducing the filter assembly 50 into the blood vessel 70. The expansion frame 52 is opened to the enlarged condition until the filter mesh 60 engages the walls 72 of the blood vessel 70. The balloon 16 is then inflated, pushing the stent 20 against the plaque 76, opening the treated region 74. As before, the stent 20 substantially permanently engages the plaque 76 and becomes part of the lumen 72 of the vessel 70. After the balloon 16 is deflated, the expansion frame 52 of the filter assembly 50 is closed to the contracted condition, and the filter assembly 50 is withdrawn into the lumen 19. The stent catheter 10 is then withdrawn from the patient using conventional procedures.

Alternatively, a self-expanding stent may be substituted for the expandable stent described above. Generally, the stent is compressed onto a catheter, and a sheath is introduced over the catheter and stent. The sheath serves to retain the stent in its compressed form until time of deployment. The catheter is percutaneously introduced into a patient and directed to the target location within the vessel. With the stent in position, the catheter is fixed and the sheath is withdrawn proximally. Once exposed within the blood vessel, the stent automatically expands radially, until it substantially engages the walls of the blood vessel, thereby trapping the embolic material and dilating the vessel. The catheter and sheath are then removed from the patient.

The filter assembly 50 generally described above has a number of possible configurations. Hereinafter reference is generally made to the filter device described above having a separate sheath, although the same filter assemblies may be incorporated directly into the stent catheter.

Turning to Figs. 4A, 4B, and 4C, another embodiment of the filter device 30 is shown, namely a sheath 32 having a guidewire 40 in its lumen 33 and a filter assembly 50 extending from the distal end 36 of sheath 32. The filter assembly 50



comprises a plurality of struts 54 and filter mesh 60. The guidewire 40 continues distally through the filter mesh 60 to the closed end region 62. The proximal ends 56 of the struts 54 are attached to the distal end 36 of the sheath 32, while the distal ends 58 of the struts 54 are attached to the distal end 42 of the guidewire. In Fig. 4A, showing the contracted condition, the struts 54 are substantially straight and extend distally. At an intermediate region 57, the open end 64 of the filter mesh 60 is attached to the struts 54 using the methods previously described. The filter mesh 60 may be attached to the struts 54 only at the intermediate region 57 or preferably continuously from the intermediate region 57 to the distal ends 58.

In addition, at the intermediate region 57, the struts 54 are notched or otherwise designed to buckle or bend outwards when compressed. Between the intermediate region 57 of the struts 54 and the distal end 36 of the sheath 32, the guidewire 40 includes a locking member 80, preferably an annular-shaped ring made of stainless steel, fixedly attached thereon. Inside the lumen 33 near the distal end 36, the sheath 32 has a recessed area 82 adapted to receive the locking member 80.

The guidewire 40 and filter assembly 50 are included in a sheath 32 as previously described, which is introduced into a blood vessel 70, as shown in Fig. 4A, downstream of the stenosed region (not shown). With the sheath 32 substantially held in position, the guidewire 40 is pulled proximally. This causes the struts 54 to buckle and fold outward at the intermediate region 57, opening the open end 64 of the filter mesh 60 as shown in Fig. 4B. As the guidewire 40 is pulled, the locking member 80 enters the lumen 33, moving proximally until it engages the recessed area 82, locking the expansion frame in its enlarged condition, as shown in Fig. 4C. With the expansion frame 52 in its enlarged condition, the open end 64 of the filter mesh 60 substantially engages the walls 72 of the blood vessel 70.

After the stent is delivered (not shown), the expansion frame 52 is closed by pushing the guidewire 40 distally. This pulls the struts 54 back in towards the guidewire 40, closing the open end 64 of the filter mesh 60 and holding any loose embolic material within the filter assembly 50.

As a further modification of this embodiment, the entire sheath 32 and filter assembly 50 may be provided within an outer sheath or catheter (not shown) to protect the filter assembly 50 during introduction into the vessel. Once the device is in the desired location, the sheath 32 is held in place and the outer sheath is withdrawn proximally, exposing the filter assembly 50 within the blood vessel 70. After the filter assembly 50 is used and closed, the sheath 32 is pulled proximally until the filter assembly 50 completely enters the outer sheath, which may then be removed.

Turning to Figs. 5A, 5B and 5C, another embodiment of the filter assembly 50 is shown. The proximal ends 56 of the plurality of struts 54 are substantially fixed to the distal end 36 of the sheath 32. The distal ends 58 may terminate at the open end 64 of the filter mesh 60, although preferably, the struts 54 extend distally through the filter mesh 60 to the closed end region 62, where they are attached to the distal end 42 of the guidewire 40.

Referring to Fig. 5A, the filter assembly 50 is shown in its contracted condition. The guidewire 40 has been rotated torsionally, causing the struts 54 to helically twist along the longitudinal axis of the guidewire 40 and close the filter mesh 60. The filter assembly 50 is introduced into a blood vessel 70 as already described, either exposed on the end of the sheath 32 or, preferably, within an outer sheath (not shown) as described above.

Once in position, the sheath 32 is fixed, and the guidewire 40 is rotated torsionally in relation to the sheath 32. As shown in Fig. 5B, the struts 54, which are biased to move radially towards the wall 72 of the vessel 70, unwind as the guidewire 40 is rotated, opening the open end 64 of the filter mesh 60. Once the struts 54 are untwisted, the expansion frame in its enlarged condition causes the open end 64 of the filter mesh 60 to substantially engage the walls 72 of the vessel 70, as shown in Fig. 5C.

After the stent is delivered (not shown), the guidewire 40 is again rotated, twisting the struts 54 back down until the expansion frame 52 again attains the contracted condition of Fig. 5A. The sheath 32 and filter assembly 50 are then removed from the blood vessel 70.

Another embodiment of the filter assembly 50 is shown in Figs. 6A and 6B. The struts 54 at their proximal ends 56 are mounted on or in contact with guidewire 40, and their distal ends 58 are connected to form the expansion frame 52, and are biased to expand radially at an intermediate region 57. The proximal ends 56 are attached to the distal end 42 of the guidewire 40 with the distal ends 58 being extended distally from sheath 32. Filter mesh 60 is attached to the struts 54 at the intermediate region 57. If the filter assembly 50 is introduced in an antegrade orientation as previously described, the filter mesh 60 is typically attached from the intermediate region 57 to the distal ends 58 of the struts 54, as indicated in Fig. 6A. Alternatively, if introduced in a retrograde orientation, it is preferable to attach the filter mesh 60 between the intermediate region 57 to the proximal ends 56 of the struts 54, as shown in Fig. 6B, thus directing the interior of the filter mesh upstream to capture any embolic material therein.

The filter assembly 50 is provided with the struts 54 compressed radially in a contracted condition in the lumen 33 of the sheath 32 (not shown). The filter assembly 50 is introduced into the blood vessel 70 by directing the guidewire distally. As the expansion frame 52 enters the blood vessel, the struts 54 automatically expand radially into the enlarged condition shown in Figs. 6A and 6B, thereby substantially engaging the open end 64 of the filter mesh 60 with the walls 72 of the blood vessel 70. To withdraw the filter assembly 50 from the vessel 70, the guidewire 40 is simply pulled proximally. The struts 54 contact the distal end 36 of the sheath 32 as they enter the lumen 33, compressing the expansion frame 52 back into the contracted condition.

Fig. 8A presents another embodiment of the filter assembly 50 similar to that just described. The expansion frame 52 comprises a plurality of struts 54 having a filter mesh 60 attached thereon. Rather than substantially straight struts bent at an intermediate region, however, the struts 54 are shown having a radiused shape biased to expand radially when the filter assembly 50 is first introduced into the blood vessel 70. The filter mesh 60 has a substantially hemispherical shape, in lieu of the conical shape previously shown.

Optionally, as shown in Fig. 8B, the filter mesh 60 may include gripping

hairs 90, preferably made from nylon, polyethylene, or polyester, attached around the outside of the open end 64 to substantially minimize undesired movement of the filter mesh 60. Such gripping hairs 90 may be included in any embodiment presented if additional engagement between the filter mesh 60 and the walls 72 of the vessel 70 is desired.

Fig. 7 shows an alternative embodiment of the filter assembly 50, in which the expansion frame 52 comprises a strut 54 attached to the filter mesh 60. The open end 64 of the filter mesh 60 is biased to open fully, thereby substantially engaging the walls 72 of the blood vessel 70. The mesh material itself may provide sufficient bias, or a wire frame (not shown) around the open end 64 may be used to provide the bias to open the filter mesh 60.

The filter mesh 60 is compressed prior to introduction into the sheath 32. To release the filter assembly 50 into the blood vessel 70, the guidewire 40 is moved distally. As the filter assembly 50 leaves the lumen 33 of the sheath 32, the filter mesh 60 opens until the open end 64 substantially engages the walls 72 of the blood vessel 70. The strut 54 attached to the filter mesh 60 retains the filter mesh 60 and eases withdrawal back into the sheath 32. For removal, the guidewire 40 is directed proximally. The strut 54 is drawn into the lumen 33, pulling the filter mesh 60 in after it.

In a further alternative embodiment, Fig. 9 shows a filter assembly 50 comprising a plurality of substantially cylindrical, expandable sponge-like devices 92, having peripheral surfaces 94 which substantially engage the walls 72 of the blood vessel 70. The devices 92 are fixed to the guidewire 40 which extends centrally through them as shown. The sponge-like devices have sufficient porosity to allow blood to pass freely through them and yet to entrap undesirable substantially larger particles, such as loose embolic material. Exemplary materials appropriate for this purpose include urethane, silicone, cellulose, or polyethylene, with urethane and polyethylene being preferred.

In addition, the devices 92 may have varying porosity, decreasing along the longitudinal axis of the guidewire. The upstream region 96 may allow larger particles, such as embolic material, to enter therein, while the downstream region

98 has sufficient density to capture and contain such material. This substantially decreases the likelihood that material will be caught only on the outer surface of the devices, and possibly come loose when the devices is drawn back into the sheath.

5           The devices 92 are compressed into the lumen 33 of the sheath 32 (not shown), defining the contracted condition. They are introduced into the blood vessel 70 by pushing the guidewire 40 distally. The devices 92 enter the vessel 70 and expand substantially into their uncompressed size, engaging the walls 72 of the vessel 70. After use, the guidewire 40 is pulled proximally, compressing the  
10 devices 92 against the distal end 36 of the sheath 32 and directing them back into the lumen 33.

Turning to Fig. 10, another embodiment of the present invention is shown, that is, a stent catheter 10 having a filter assembly 50 provided directly on its outer surface 13. The stent catheter 10 includes similar elements and materials to those  
15 already described, namely a catheter 12, an inflatable balloon 16 near the distal end 14 of the catheter 12, and a stent 20 compressed over the balloon 16. Instead of providing a filter assembly 50 on a guidewire, however, the filter assembly 50 typically comprises an expansion frame 52 and filter mesh 60 attached directly to the outer surface 13 of the catheter 12. Preferably, the expansion frame 52 is  
20 attached to the catheter 12 in a location proximal of the stent 20 for use in retrograde orientations, although optionally, the expansion frame 52 may be attached distal of the stent 20 and used for antegrade applications.

The filter assembly 50 may take many forms similar to those previously described for attachment to a guidewire. In Fig. 10, the expansion frame 52  
25 includes a plurality of radially biased struts 54, having proximal ends 56 and distal ends 58. The proximal ends 56 of the struts 54 are attached to the outer surface 13 of the catheter 12 proximal of the stent 20, while the distal ends 58 are loose. Filter mesh 60, similar to that already described, is attached to the struts 54 between the proximal ends 56 and the distal ends 58, and optionally to the outer  
30 surface 13 of the catheter 12 where the proximal ends 56 of the struts 52 are attached.

Prior to use, a sheath 132 is generally directed over the catheter 12. When the sheath engages the struts 54, it compresses them against the outer surface 13 of the catheter 12. The catheter 12 and the sheath 132 are then introduced into the patient, and directed to the desired location. Once the stent 20 is in position, the catheter 12 is fixed and the sheath 132 is drawn proximally. As the struts 58 enter the blood vessel 70, the distal ends 58 move radially, opening the filter mesh 60. Once the filter assembly 50 is fully exposed within the blood vessel 70, the distal ends 58 of the struts 54, and consequently the open end 64 of the filter mesh 60, substantially engage the walls 72 of the blood vessel 70.

After the stent is deployed, the sheath 132 is pushed distally. As the struts 54 enter the lumen 133 of the sheath 132, they are compressed back against the outer surface 13 of the catheter 12, thereby containing any captured material in the filter mesh 60. The catheter 12 and sheath 132 are then withdrawn from the vessel 70.

Turning to Figs. 11A and 11B, an alternative embodiment of the expansion frame 50 is shown. The proximal ends 56 of the struts 54 are attached or in contact with the outer surface 13 of the catheter 12. The struts 54 have a contoured radius biased to direct an intermediate region 57 radially. Filter mesh 60 is attached between the intermediate region 57 and the proximal ends 56, or between the intermediate region and the distal end (not shown). Fig. 11A shows the filter assembly 50 in its contracted condition, with a sheath 132 covering it. The sheath 132 compresses the struts 54 against the outer surface 13 of the catheter 12, allowing the device to be safely introduced into the patient. Once in position, the sheath 132 is pulled proximally as shown in Fig. 11B. As the distal end 136 of the sheath 132 passes proximal of the filter assembly 50, the struts 54 move radially, causing the intermediate region 57 of the struts 54 and the open end of the filter mesh 60 to substantially engage the walls 72 of the blood vessel 70. After use, the sheath 132 is directed distally, forcing the struts 54 back against the catheter 12 and containing any material captured within the filter mesh 60.

In another embodiment of the present invention, shown in Figs. 12A and 12B, a stent catheter 10, similar to those previously described, is provided with a

fluid operated filter assembly 50 attached on or near the distal end 14 of the catheter 12. The catheter 12 includes a first inflation lumen 18 for the stent balloon 16, and a second inflation lumen 19 for inflating an expansion frame 52 for the filter assembly 50. The expansion frame 52 generally comprises an inflatable balloon 102, preferably having a substantially annular shape. The balloon 102 generally comprises a flexible, substantially resilient material, such as silicone, latex, or urethane, but with urethane being preferred.

The second inflation lumen 19 extends to a region at or near to the distal end 14 of the catheter 12, and then communicates with the outer surface 13, or extends completely to the distal end 14. A conduit 104 extends between the balloon 102 and the inflation lumen 19. The conduit 104 may comprise a substantially flexible tube of material similar to the balloon 102, or alternatively it may be a substantially rigid tube of materials such as polyethylene. Optionally, struts or wires 106 are attached between the balloon 102 and the catheter 12 to retain the balloon 12 in a desired orientation. Filter mesh 60, similar to that previously described, is attached to the balloon 102.

Turning more particularly to Fig. 12A, the filter assembly 50 is shown in its contracted condition. The balloon 102 is adapted such that in its deflated condition it substantially engages the outer surface 13 of the catheter 12. This retains the filter mesh 60 against the catheter 12, allowing the catheter 12 to be introduced to the desired location within the patient's blood vessel 70. The catheter 12 is percutaneously introduced into the patient and the stent 20 is positioned within the occluded region 74. Fluid, such as saline solution, is introduced into the lumen 19, inflating the balloon 102. As it inflates, the balloon 102 expands radially and moves away from the outer surface 13 of the catheter 12.

As shown in Fig. 12B, once the balloon 102 is fully inflated to its enlarged condition, it substantially engages the walls 72 of the blood vessel 70 and opens the filter mesh 60. Once the stent 20 is delivered and the stent balloon 16 is deflated, fluid is drawn back out through the inflation lumen 19, deflating the balloon 102. Once deflated, the balloon 102 once again engages the outer surface 13 of the catheter 12, closing the filter mesh 60 and containing any embolic

material captured therein. The catheter 12 is then withdrawn from the patient.

Alternatively, the filter assembly 50 just described may be mounted in a location proximal to the stent 20 as shown in Figs. 13A and 13B. The open end 64 of the filter mesh 60 is attached to the balloon 102, while the closed end 62 is  
5 attached to the outer surface 13 of the catheter 12, thereby defining a space for capturing embolic material. In the contracted condition shown in Fig. 13A, the balloon 102 substantially engages the outer surface 13 of the catheter 12, thereby allowing the catheter 10 to be introduced or withdrawn from a blood vessel 70. Once the stent 20 is in position across a stenosed region 74, the balloon 102 is  
10 inflated, moving it away from the catheter 12, until it achieves its enlarged condition, shown in Fig. 13B, whereupon it substantially engages the walls 72 of the blood vessel 70.

A detailed longitudinal view of a filter guidewire is shown in Fig. 15. Guidewire 40 comprises inner elongate member 207 surrounded by a second  
15 elongate member 201, about which is wrapped wire 211 in a helical arrangement. Guidewire 40 includes enlarged segment 202, 208 which houses a series of radially biased struts 203. Helical wires 211 separate at cross-section 205 to expose the eggbeater filter contained within segment 202. Guidewire 40 includes a floppy atramatic tip 204 which is designed to navigate through narrow, restricted vessel  
20 lesions. The eggbeater filter is deployed by advancing distally elongate member 201 so that wire housing 211 separates at position 205 as depicted in Fig. 15A. Elongate member 207 may be formed from a longitudinally stretchable material which compresses as the struts 203 expand radially. Alternatively, elongate member 207 may be slidably received within sheath 201 to allow radial expansion  
25 of struts 203 upon deployment. The filter guidewire may optionally include a coil spring 206 disposed helically about elongate member 207 in order to cause radial expansion of struts 203 upon deployment.

A typical filter guidewire will be constructed so that the guidewire is about 5F throughout segment 208, 4F throughout segment 209, and 3F throughout  
30 segment 210. The typical outer diameter in a proximal region will be 0.012–0.035 inches, more preferably 0.016–0.022 inches, more preferably 0.018 inches. In the



distal region, a typical outer diameter is 0.020–0.066 inches, more preferably 0.028–0.036 inches, more preferably 0.035 inches. Guidewire length will typically be 230–290 cm, more preferably 260 cm for deployment of a balloon catheter. It should be understood that reducing the dimensions of a percutaneous medical instrument to the dimensions of a guidewire as described above is a significant technical hurdle, especially when the guidewire includes a functioning instrument such as an expansible filter as disclosed herein. It should also be understood that the above parameters are set forth only to illustrate typical device dimensions, and should not be considered limiting on the subject matter disclosed herein.

In use, a filter guidewire is positioned in a vessel at a region of interest. The filter is deployed to an expanded state, and a medical instrument such as a catheter is advanced over the guidewire to the region of interest. Angioplasty, stent deployment, rotoblader, atherectomy, or imaging by ultrasound or Doppler is then performed at the region of interest. The medical/interventional instrument is then removed from the patient. Finally, the filter is compressed and the guidewire removed from the vessel.

A detailed depiction of an eggbeater filter is shown in Figs. 16, 16A, 16B, and 16C. With reference to Fig. 16, the eggbeater filter includes pressure wires 212, primary wire cage 213, mesh 52, and optionally a foam seal 211 which facilitates substantial engagement of the interior lumen of a vessel wall and conforms to topographic irregularities therein. The eggbeater filter is housed within catheter sheath 32 and is deployed when the filter is advanced distally beyond the tip of sheath 32. This design will accommodate a catheter of size 8F (0.062 inches, 2.7 mm), and for such design, the primary wire cage 213 would be 0.010 inches and pressure wires 212 would be 0.008 inches. These parameters can be varied as known in the art, and therefore should not be viewed as limiting. Figs. 16A and 16B depict the initial closing sequence at a cross-section through foam seal 214. Fig. 16C depicts the final closing sequence.

Figs. 17 and 17A depict an alternative filter guidewire which makes use of a filter scroll 215 disposed at the distal end of guidewire 40. Guidewire 40 is

torsionally operated as depicted at 216 in order to close the filter, while reverse operation (217) opens the filter. The filter scroll may be biased to automatically spring open through action of a helical or other spring, or heat setting.

Alternatively, manual, torsional operation opens the filter scroll. In this design,  
5 guidewire 40 acts as a mandrel to operate the scroll 215.

An alternative embodiment of a stent deployment blood filtration device is depicted in Figs. 18, 18A, and 18B. With reference to Fig. 18, catheter 225 includes housing 220 at its proximal end 221, and at its distal end catheter 225 carries stent 223 and expandable filter 224. In one embodiment, expandable filter  
10 224 is a self-expanding filter device optionally disposed about an expansion frame.

In another embodiment, filter 224 is manually operable by controls at proximal region 221 for deployment. Similarly, stent 223 can be either a self-expanding stent as discussed above, or a stent which is deployed using a balloon or other radially expanding member. Restraining sheath 222 encloses one or both of filter  
15 224 and stent 223. In use, distal region 226 of catheter 225 is disposed within a region of interest, and sheath 222 is drawn proximally to first exposed filter 224 and then exposed stent 223. As such, filter 224 deploys before stent 223 is radially expanded, and therefore filter 224 is operably in place to capture any debris dislodged during stent deployment as depicted in Fig. 18A. Fig. 18B shows  
20 an alternative embodiment which employs eggbeater filter 224 in the distal region.

An alternative design for the construction of an eggbeater filter is shown in Fig. 19. This device includes inner sheath 231, outer sheath 230, and a plurality of struts 232 which are connected to outer sheath 230 at a proximal end of each strut, and to inner sheath 231 at a distal end of each strut. Filter expansion is  
25 accomplished by moving inner sheath 231 proximal relative to outer sheath 230, which action causes each strut to buckle outwardly. It will be understood that the struts in an eggbeater filter may be packed densely to accomplish blood filtration without a mesh, or may include a mesh draped over a proximal portion 233 or a distal portion 234, or both.

30 In another embodiment, a filter guidewire is equipped with a distal imaging device as shown in Fig. 20. Guidewire 40 includes eggbeater filter 224 and

restraining sheath 222 for deployment of filter 224. The distal end of guidewire 40 is equipped with imaging device 235 which can be any of an ultrasound transducer or a Doppler flow velocity meter, both capable of measuring blood velocity at or near the end of the guidewire. Such a device provides valuable information for assessment of relative blood flow before and after stent deployment. Thus, this device will permit the physician to determine whether the stent has accomplished its purpose or been adequately expanded by measuring and comparing blood flow before and after stent deployment.

In use, the distal end of the guidewire is introduced into the patient's vessel with the sheath covering the expandable filter. The distal end of the guidewire is positioned so that the filter is downstream of a region of interest and the sheath and guidewire cross the region of interest. The sheath is slid toward the proximal end of the guidewire and removed from the vessel. The expandable filter is uncovered and deployed within the vessel downstream of the region of interest. A percutaneous medical instrument is advanced over the guidewire to the region of interest and a procedure is performed on a lesion in the region of interest. The percutaneous medical instrument can be any surgical tool such as devices for stent delivery, balloon angioplasty catheters, atherectomy catheters, a rotoblader, an ultrasound imaging catheter, a rapid exchange catheter, an over-the-wire catheter, a laser ablation catheter, an ultrasound ablation catheter, and the like. Embolic material generated during use of any of these devices on the lesion is captured before the expandable filter is removed from the patient's vessel. The percutaneous instrument is then withdrawn from the vessel over the guidewire. A sheath is introduced into the vessel over the guidewire and advanced until the sheath covers the expandable filter. The guidewire and sheath are then removed from the vessel.

Human aortic anatomy is depicted in Fig. 21. During cardiac surgery, bypass cannula 243 is inserted in the ascending aorta and either balloon occlusion or an aortic cross-clamp is installed upstream of the entry point for cannula 243. The steps in a cardiac procedure are described in Barbut et al., U.S. Application Serial No. 08/842,727, filed April 16, 1997, and the level of debris dislodgment is

described in Barbut et al., "Cerebral Emboli Detected During Bypass Surgery Are Associated With Clamp Removal," *Stroke*, 25(12):2398-2402 (1994), which is incorporated herein by reference in its entirety. Fig. 21 demonstrates that the decoupling of the filter from the bypass cannula presents several avenues for filter deployment. As discussed in Maahs, U.S. Application Serial No. 08/853,165, filed May 8, 1997, and incorporated herein by reference, a modular filter may be deployed through cannula 243 either upstream 244 or downstream 245. In accordance with the present disclosure, a filter may be deployed upstream of the innominate artery within the aorta by using a filter guidewire which is inserted at 10 240 through a femoral artery approach. Alternatively, filter guidewire may be inserted through route 241 by entry into the left subclavian artery or by route 242 by entry through the right subclavian artery, both of which are accessible through the arms. The filter guidewire disclosed herein permits these and any other routes for accessing the ascending aorta and aortic arch for blood filtration.

15 In another embodiment, a generalized filter guidewire is depicted in Fig. 22. Fig. 23 shows guidewire 40 having sleeve 250 disposed thereabout. Sleeve 250 includes longitudinally slitted region 251 which is designed to radially expand when compressed longitudinally. Thus, when the distal end of sleeve 250 is pulled proximally, the slitted region 251 buckles radially outwardly as shown in Fig. 23A to provide a form of eggbeater filter. The expanded cage thus formed may 20 optionally include mesh 52 draped over a distal portion, a proximal portion, or both.

In use, a stent catheter, such as those previously described, is used in a retrograde application, preferably to prevent the detachment of mobile aortic plaque deposits within the ascending aorta, the aortic arch, or the descending 25 aorta. Preferably, the stent catheter is provided with a filter assembly, such as that just described, attached to the catheter proximal of the stent. Alternatively, a stent catheter without any filter device, may also be used. The stent catheter is percutaneously introduced into the patient and directed to the desired region. 30 Preferably, the catheter is inserted into a femoral artery and directed into the aorta, or is introduced into a carotid artery and directed down into the aorta. The stent is

centered across the region which includes one or more mobile aortic deposits.

If a filter assembly is provided on the catheter, it is expanded to its enlarged condition before the stent is deployed in order to ensure that any material inadvertently dislodged is captured by the filter. Alternatively, a sheath having a guidewire and filter assembly similar to those previously described may be  
5 separately percutaneously introduced downstream of the region being treated, and opened to its enlarged condition.

The stent balloon is inflated, expanding the stent to engage the deposits. The stent forces the deposits against the wall of the aorta, trapping them. When  
10 the balloon is deflated, the stent substantially maintains its inflated cross-section, substantially permanently containing the deposits and forming a portion of the lumen of the vessel. Alternatively, a self-expanding stent may be delivered, using a sheath over the stent catheter as previously described. Once the stent has been deployed, the filter assembly is closed, and the stent catheter is withdrawn using  
15 conventional methods.

Unlike the earlier embodiments described, this method of entrapping aortic plaque is for a purpose other than to increase luminal diameter. That is, mobile aortic deposits are being substantially permanently contained beneath the stent to protect a patient from the risk of embolization caused by later detachment of  
20 plaque. Of particular concern are the ascending aorta and the aortic arch. Loose embolic material in these vessels presents a serious risk of entering the carotid arteries and traveling to the brain, causing serious health problems or possibly even death. Permanently deploying a stent into such regions substantially reduces the likelihood of embolic material subsequently coming loose within a patient, and  
25 allows treatment without expensive intrusive surgery to remove the plaque.

While the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the invention is not to be limited to the particular forms or methods disclosed, but to the contrary, the  
30 invention is to cover all modifications, equivalents and alternatives falling within the spirit and scope of the appended claims.

**WHAT IS CLAIMED IS:**

1. A percutaneous catheter having filter and stent deployment capabilities, comprising:
  - a catheter body having a proximal and a distal end, and having a proximal and a distal region;
  - an expandable stent disposed about the distal region of the catheter body, the stent having a first diameter which permits intraluminal delivery of the stent into a body passageway and which places the stent in close proximity to the catheter body, and having a second expanded diameter adapted to substantially engage a wall of the body passageway;
  - an expansion frame disposed near the distal region of the catheter body which is expandable between a contracted and an enlarged condition;
  - filter mesh attached to the expansion frame; and
  - a sheath which is shaped to receive the catheter body and retain the stent at the first diameter and retain the expansion frame in the contracted condition, wherein during use, the sheath is pulled back to release the expansion frame and the stent.
2. The catheter of claim 1 wherein the expansion frame is distal to the stent.
3. The catheter of claim 1, wherein the expansion frame comprises a plurality of struts which, upon activation, bend outwardly to the enlarged condition.
4. The catheter of claim 1, wherein the expansion frame comprises radially biased struts attached to an outer surface of the catheter body.
5. The catheter of claim 4, wherein the proximal end of each strut is in contact with the catheter body and the distal end of each strut is in contact with the catheter body, and wherein the struts expand to the shape of an eggbeater.

6. The catheter of claim 3, wherein the catheter body includes a distal segment which can be moved longitudinally relative to the catheter body, and wherein the proximal end of each strut is in contact with the catheter body and the distal end of each strut is in contact with the distal segment, and wherein the struts expand radially when the distal segment is pulled toward the proximal region of the catheter body.

7. The catheter of claim 1, wherein the stent and the expansion frame are self-expanding.

8. The catheter of claim 1, wherein the expansion frame comprises an inflation seal.

9. The catheter of claim 8, further comprising an inflation system comprising a first lumen adapted to receive pressurized fluid and a second lumen adapted to evacuate gas, and wherein the inflation seal further includes an entry port in fluid communication with the first lumen of the inflation system and an exit port in fluid communication with the second lumen of the inflation system, so that when fluid is advanced through the first lumen, the fluid enters the inflation seal and forces gas from the inflation seal through the second lumen, thereby purging the system of gas.

10. The catheter of claim 8, wherein the inflation seal comprises a tubular balloon which encloses a chamber and wherein the entry port and exit port are in close proximity, and wherein a septum is disposed between the entry and exit ports.

11. The catheter of claim 1, wherein the stent is removable.

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12. The catheter of claim 1, wherein the stent is self-expanding.

13. The catheter of claim 1, wherein the stent comprises stainless steel material.

5 14. The catheter of claim 1, wherein the stent comprises nitinol material.

15 15. The catheter of claim 1, wherein the stent has a shape selected from the group consisting of a tube, a sheet, a wire, a mesh, and a spring.

16. A filter device for capturing embolic material in a blood vessel, comprising:

a substantially flexible sheath having a distal end and a proximal end, and having a lumen extending between the distal end and the proximal end;

15 a guidewire having a distal end, a proximal end, and proximal and distal regions, the guidewire being slidably insertable into the lumen of the sheath and longitudinally movable relative to the sheath;

an expansion frame attached to the distal region of the guidewire, the expansion frame being expandable between a contracted and an enlarged condition; and

20 filter mesh attached to the expansion frame.

17. The filter device of claim 16, wherein the expansion frame comprises a plurality of radially biased struts.

25 18. The filter device of claim 17, wherein the proximal end of each strut is in contact with the guidewire and the distal end of each strut is in contact with guidewire, and wherein the struts expand to the shape of an eggbeater.

30 19. The filter device of claim 16, wherein the expansion frame is torsionally disposed on the guide wire, and wherein the expansion frame is



activated by rotating the guide wire in relation to the sheath.

20. The filter device of claim 16, wherein the guidewire includes a distal segment which can be moved longitudinally relative to the guidewire, and wherein the proximal end of each strut is in contact with the guidewire and the distal end of each strut is in contact with the distal segment of the guidewire, and wherein the struts expand to the shape of an eggbeater.

21. The filter device of claim 16, wherein the expansion frame comprises radially expandable struts, activated by moving the guide wire longitudinally in relation to the sheath.

22. A method for protecting a patient from embolization during stent deployment within an artery, comprising the steps of:  
providing a catheter comprising a catheter body having proximal and distal ends, a proximal and a distal region, and an expandable stent associated with the distal region;

introducing the distal end of the catheter body into the patient's artery while the stent is in a contracted condition which permits intraluminal delivery;  
deploying an expandable blood filter within the artery and downstream of a region of interest;  
positioning the stent within the region of interest; and  
expanding the stent at the region of interest.

23. The method of claim 22, wherein the artery is the aorta.

24. The method of claim 22, wherein the region of interest is at least one of the ascending aorta, descending aorta, aortic arch, common carotid artery, external and internal carotid arteries, brachiocephalic trunk, middle cerebral artery, anterior cerebral artery, posterior cerebral artery, vertebral artery, basilar artery, subclavian artery, brachial artery, axillary artery, iliac artery, renal artery, femoral

artery, popliteal artery, celiac artery, superior mesenteric artery, inferior mesenteric artery, anterior tibial artery, and posterior tibial artery.

25. The method of claim 22, wherein the artery is at least one of the  
5 carotid arteries.

26. The method of Claim 22, wherein the catheter further includes a  
balloon disposed about the distal region, wherein the stent is associated with the  
balloon, and wherein the step of expanding the stent includes the step of inflating the  
10 balloon.

27. The method of Claim 22, wherein the expandable blood filter is  
operably associated with the catheter body, and wherein the step of deploying the  
expandable filter includes the step of operating controls from the proximal region of  
15 the catheter body to expand the blood filter to cover a substantial portion of the  
cross-sectional area of the artery.

28. The method of Claim 22, wherein the step of deploying the  
expandable filter includes the steps of:  
20 inserting an introducer sheath into the artery downstream of the region of  
interest;  
advancing a blood filter catheter through the introducer sheath and into the  
artery; and  
operating controls from a proximal region of the blood filter catheter to  
25 expand the blood filter to cover a substantial portion of the cross-sectional area of  
the artery.

29. A method for protecting a patient from embolization, comprising the  
steps:  
30 providing a catheter comprising a catheter body having proximal and distal  
ends, a proximal and a distal region, and an expandable stent associated with the

distal region;

introducing the distal end of the catheter body into an artery of the patient while the stent is maintained in a contracted condition which permits intraluminal delivery;

5       positioning the stent within a region of interest, the region of interest comprising an intraluminal site of attachment of mobile aortic plaque within at least one of the ascending aorta, the aortic arch, and the carotid arteries; and

expanding the stent at the region of interest so that the stent reaches an expanded diameter which places it in firm contact with the mobile aortic plaque,  
10       whereby the expanded stent prevents detachment of the mobile aortic plaque.

30.     The method of Claim 29, further comprising the step of deploying an expandable blood filter within the aorta and downstream of the region of interest.

15       31.     A method of protecting a patient from embolization during a percutaneous procedure on a vessel, comprising the steps of:

providing a guidewire having proximal and distal ends, a proximal and a distal region, an expandable filter associated with the distal region, and a removable sheath which covers the expandable filter and is slidable over the  
20       guidewire;

introducing the distal end of the guidewire into the patient's vessel with the sheath covering the expandable filter, and positioning the filter downstream of a region of interest, wherein the sheath and guidewire cross the region of interest;

25       retracting the sheath, wherein the expandable filter is uncovered;  
deploying the expandable filter by manual operation of an actuator against the action of a spring;

advancing over the guidewire a percutaneous instrument to the region of interest, and performing a procedure on a lesion at the region of  
30       interest, and

collapsing the expandable filter by releasing the spring.

36

wherein embolic material is generated and captured before the expandable filter is removed from the patient's vessel.

5           32.    The method of claim 31, further comprising the steps of:  
              removing the percutaneous instrument from the vessel;  
              advancing the sheath into the vessel over the guidewire until the  
sheath covers the expandable filter; and  
              removing the guidewire and sheath from the vessel.

10          33.    The method of claim 31, wherein the percutaneous instrument is a  
surgical tool.

            34.    The method of claim 33, wherein the surgical tool is a catheter for  
stent delivery.

15          35.    The method of claim 33, wherein the surgical tool is a balloon  
catheter for angioplasty.

            36.    The method of claim 33, wherein the surgical tool is a rotoblader.

20          37.    The method of claim 33, wherein the surgical tool is a catheter.

            38.    The method of claim 37, wherein the catheter is a rapid exchange  
catheter.

25          39.    The method of claim 37, wherein the catheter is an over-the-wire  
catheter.

            40.    The method of claim 31, wherein the expandable filter comprises a  
30    plurality of struts, each strut having a proximal end in contact with the guidewire  
and a distal end in contact with the guidewire, and wherein the struts expand to the

shape of an eggbeater.

41. The method of claim 31, wherein the expandable filter includes a filter mesh.

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42. The method of claim 31, wherein the expandable filter comprises a plurality of radially biased struts.

43. The method of claim 31, wherein the expandable filter comprises a plurality of radially expandable struts which are operable to expand radially outwardly.

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44. A filter device for capturing embolic material in a blood vessel, comprising:

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a substantially flexible sheath having a distal end, a proximal end, a distal region, and a proximal region, and having a lumen extending between the distal end and the proximal end;

a guidewire having a distal end, an proximal end, and proximal and distal regions, the guidewire being slidably insertable into the lumen of the sheath and longitudinally movable relative to the sheath; and

20

an expandable filter mounted on the distal region of the guidewire, the expandable filter being expandable between a contracted and an enlarged condition.

25

45. The filter device of claim 44, wherein the expandable filter includes a filter mesh.

46. The filter device of claim 44, wherein the expandable filter comprises a plurality of struts.

30

47. The filter device of claim 46, wherein each strut has a proximal end

in contact with the guidewire and a distal end in contact with the guidewire, and wherein the struts expand to the shape of an eggbeater.

5       48.     The filter device of claim 46, wherein the struts are radially biased struts.

49.     The filter device of claim 46, wherein the struts are operable to expand radially outwardly.

10       50.     The filter device of claim 49, wherein the struts are torsionally activated to expand radially outwardly.

15       51.     The filter device of claim 44, wherein the expandable filter comprises a helical filter scroll which is torsionally activated to expand radially outwardly.

52.     A method of protecting a patient from embolization during cardiac surgery, comprising the steps of:

20             providing a blood filter device having a filter disposed on a distal region of an elongate member, the filter adapted to operate at a site within the aorta of the patient and to be removed thereafter;

           introducing the blood filter device into the femoral artery and advancing the distal region of the device to the site within the aorta upstream of the innominate artery;

25             deploying the filter at the site within the aorta;  
           blocking the aorta in a region upstream of the site within the aorta;  
           and

           removing the blood filter device from the aorta,  
           wherein embolic material is generated and filtered before the blood  
30     filter device is removed from the aorta.

53. The method of claim 52, further comprising the steps of introducing a blood bypass cannula into the aorta.

54. The method of claim 53, wherein the cannula is introduced  
5 downstream of the site where the filter is deployed.

55. The method of claim 53, wherein the step of blocking the aorta includes cross-clamping the aorta.

10 56. The method of claim 53, further comprising the step of unblocking the aorta while the blood filter device is deployed within the aorta.

57. The method of claim 53, wherein said elongate member is a catheter.  
15

58. The method of claim 53, wherein said elongate member is a guidewire.

59. A method of protecting a patient from embolization during cardiac  
20 surgery, comprising the steps of:

providing a blood filter device having a filter disposed on a distal region of an elongate member, the filter adapted to operate at a site within the aorta of the patient and to be removed thereafter;

25 introducing the blood filter device into the left subclavian artery and advancing the distal region of the device to the site within the aorta upstream of the innominate artery;

deploying the filter at the site within the aorta;

blocking the aorta in a region upstream of the site within the aorta;

and

30 removing the blood filter device from the aorta,  
wherein embolic material is generated and filtered before the blood

filter device is removed from the aorta.

60. The method of claim 59, further comprising the steps of introducing a blood bypass cannula into the aorta.

5

61. The method of claim 60, wherein the cannula is introduced downstream of the site where the filter is deployed.

62. The method of claim 60, wherein the step of blocking the aorta includes cross-clamping the aorta.

10

63. The method of claim 60, further comprising the step of unblocking the aorta while the blood filter device is deployed within the aorta.

15

64. The method of claim 60, wherein said elongate member is a catheter.

65. The method of claim 60, wherein said elongate member is a guidewire.

20

66. A method of protecting a patient from embolization during cardiac surgery, comprising the steps of:

providing a blood filter device having a filter disposed on a distal region of an elongate member, the filter adapted to operate at a site within the aorta of the patient and to be removed thereafter;

25

introducing the blood filter device into the right subclavian artery and advancing the distal region of the device to the site within the aorta upstream of the innominate artery;

deploying the filter at the site within the aorta;

30

blocking the aorta in a region upstream of the site within the aorta;

and



41

removing the blood filter device from the aorta,  
wherein embolic material is generated and filtered before the blood  
filter device is removed from the aorta.

5           67.    The method of claim 66, further comprising the steps of introducing  
a blood bypass cannula into the aorta.

68.    The method of claim 67, wherein the cannula is introduced  
downstream of the site where the filter is deployed.

10

69.    The method of claim 67, wherein the step of blocking the aorta  
includes cross-clamping the aorta.

70.    The method of claim 67, further comprising the step of unblocking  
15   the aorta while the blood filter device is deployed within the aorta.

71.    The method of claim 67, wherein said elongate member is a  
catheter.

20           72.    The method of claim 67, wherein said elongate member is a  
guidewire.

73.    The catheter of claim 3, wherein the expansion frame is activated by  
inflating an annular balloon at the base of the struts.

25

74.    A method of protecting a patient from embolization during a  
percutaneous procedure on a vessel, comprising the steps of:

          providing a guidewire having proximal and distal ends, a proximal  
and a distal region, an expandable filter associated with the distal region, and a  
30   removable sheath which covers the expandable filter and is slidable over the  
guidewire;

introducing the distal end of the guidewire into the patient's vessel with the sheath covering the expandable filter, and positioning the filter downstream of a region of interest, wherein the sheath and guidewire cross the region of interest;

5                    retracting the sheath, wherein the expandable filter is uncovered;  
                      deploying the expandable filter by manual operation of an actuator against the action of a spring;

                      advancing over the guidewire a percutaneous instrument to the region of interest, and performing a procedure on a lesion at the region of  
10    interest; and

                      collapsing the expandable filter by releasing the spring,  
                      wherein embolic material is generated and captured before the expandable filter is removed from the patient's vessel.

15            75.    The method of claim 74, further comprising the steps of:  
                      removing the percutaneous instrument from the vessel;  
                      advancing the sheath into the vessel over the guidewire until the sheath covers the expandable filter; and  
                      removing the guidewire and sheath from the vessel.

20

                      76.    The method of claim 74, wherein the percutaneous instrument is a surgical tool.

                      77.    The method of claim 76, wherein the surgical tool is a catheter for  
25    stent delivery.

                      78.    The method of claim 76, wherein the surgical tool is a balloon catheter for angioplasty.

30            79.    The method of claim 76, wherein the surgical tool is a rotoblader.

80. The method of claim 76, wherein the surgical tool is a catheter.

81. The method of claim 80, wherein the catheter is a rapid exchange catheter.

5

82. The method of claim 80, wherein the catheter is an over-the-wire catheter.

83. The method of claim 74, wherein the expandable filter comprises a  
10 plurality of struts, each strut having a proximal end in contact with the guidewire  
and a distal end in contact with the guidewire, and wherein the struts expand to the  
shape of an eggbeater.

84. The method of claim 74, wherein the expandable filter includes a  
15 filter mesh.

85. The method of claim 74, wherein the expandable filter comprises a  
plurality of radially biased struts.

20 86. The method of claim 74, wherein the expandable filter comprises a  
plurality of radially expandable struts which are operable to expand radially  
outwardly.

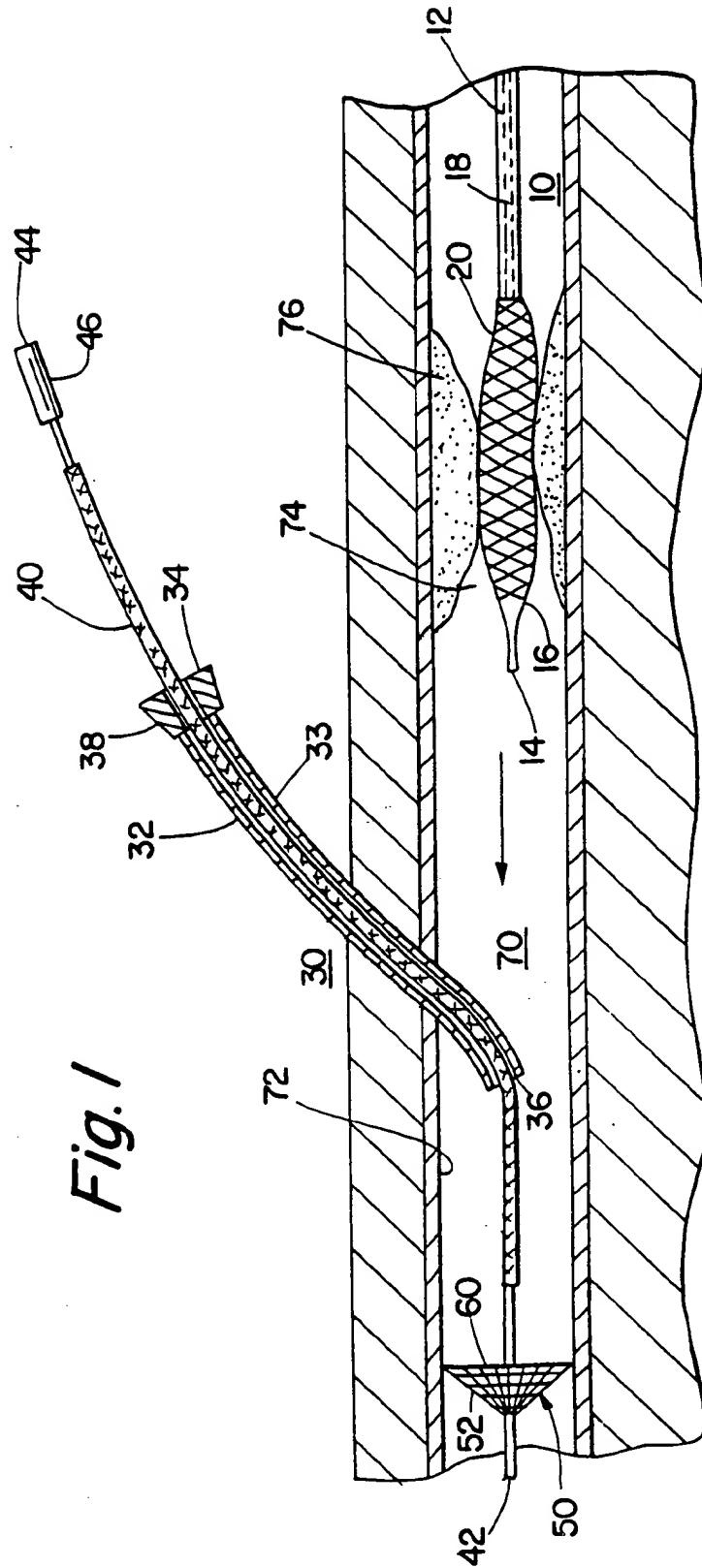
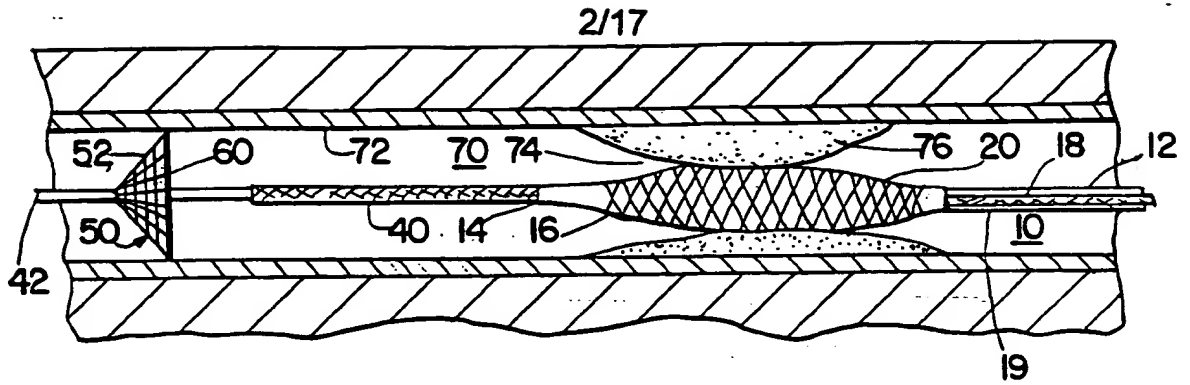
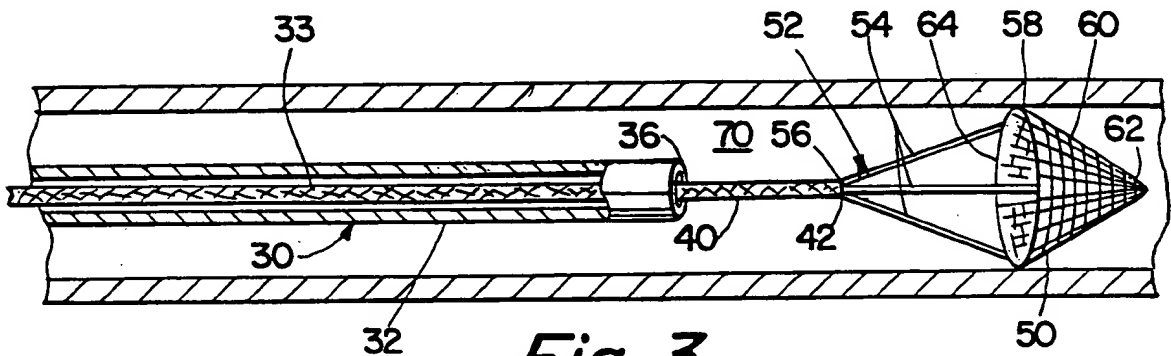


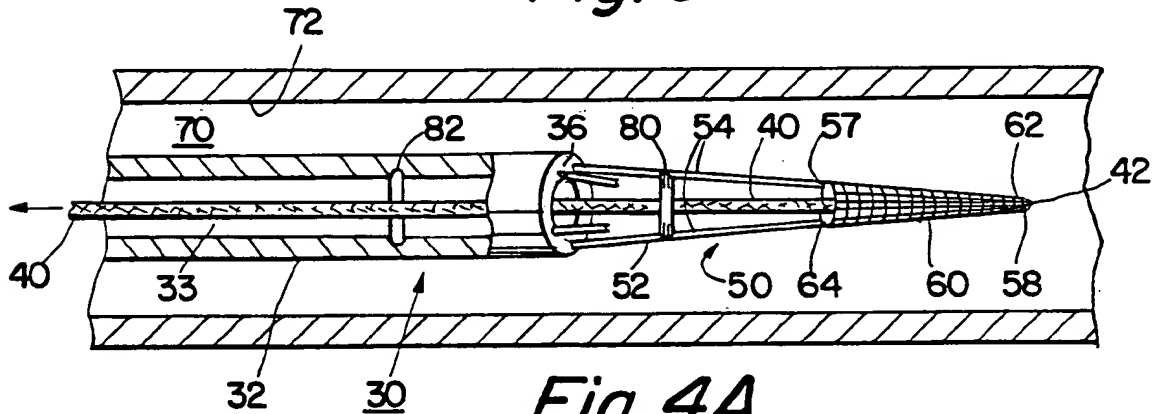
Fig. 1



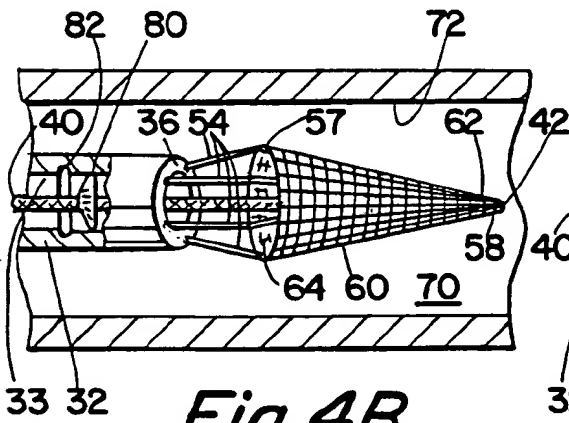
*Fig. 2*



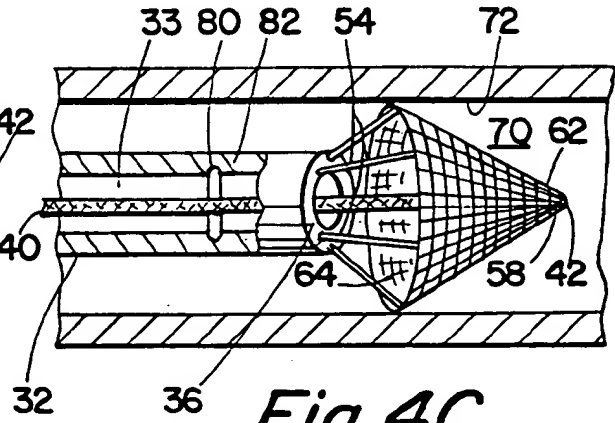
*Fig. 3*



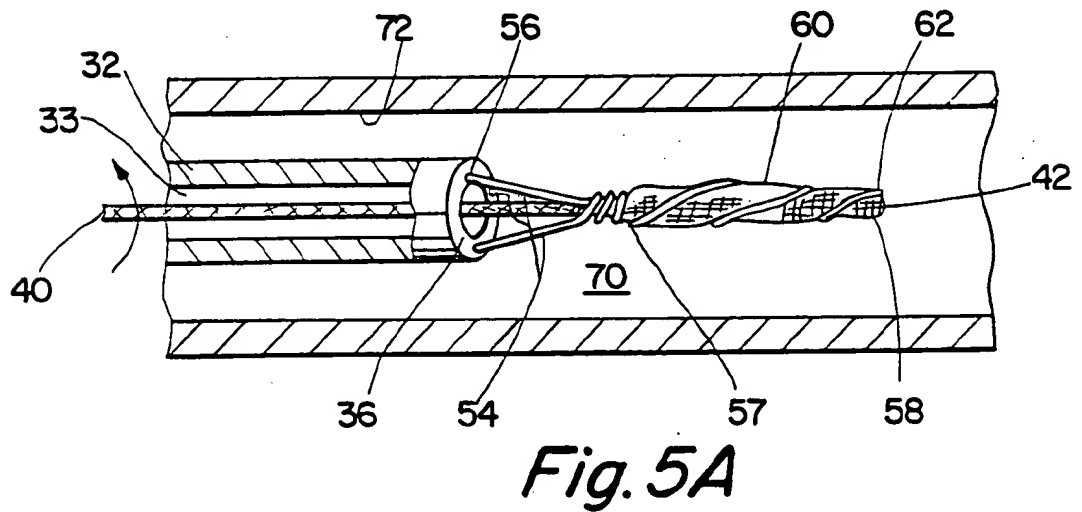
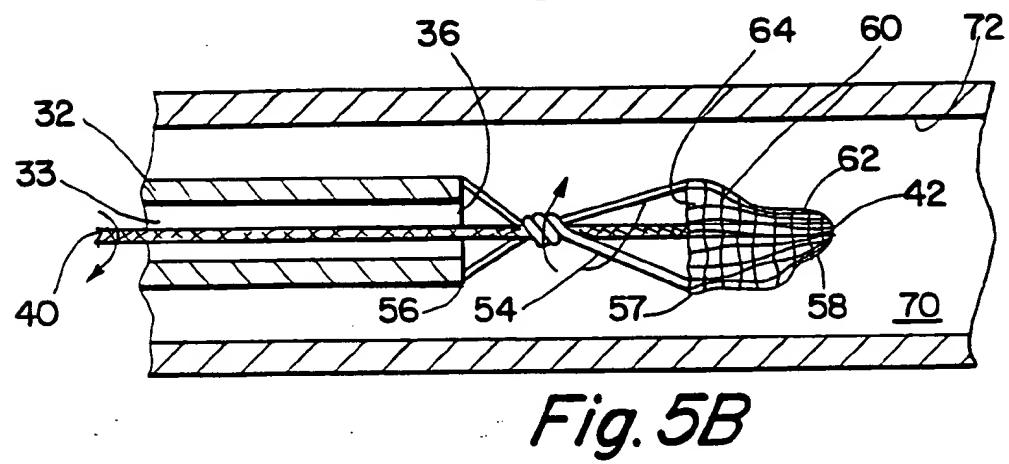
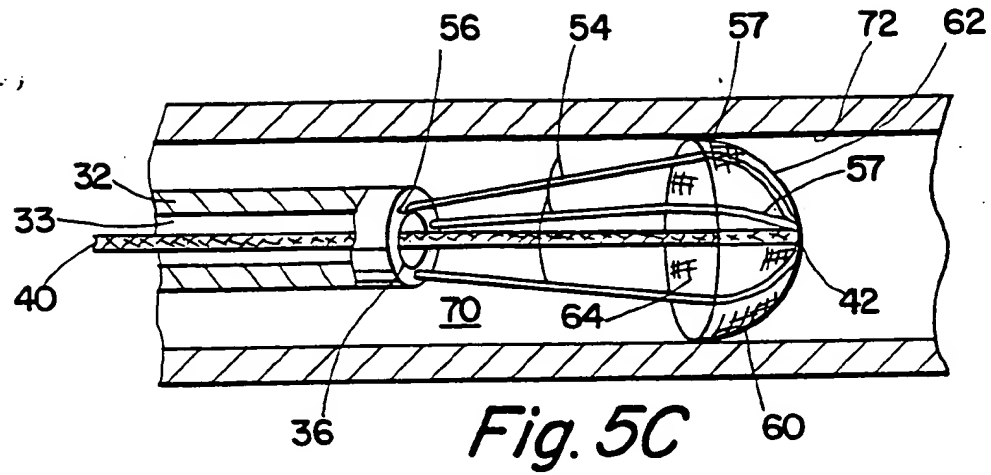
*Fig. 4A*

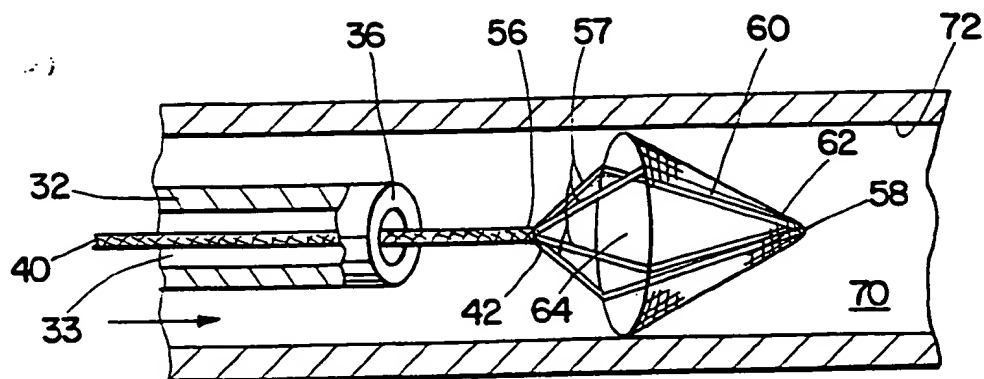
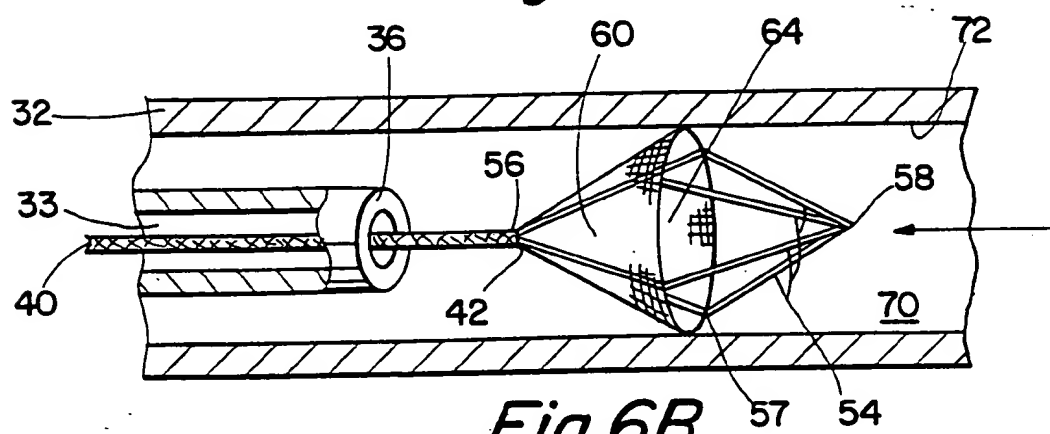
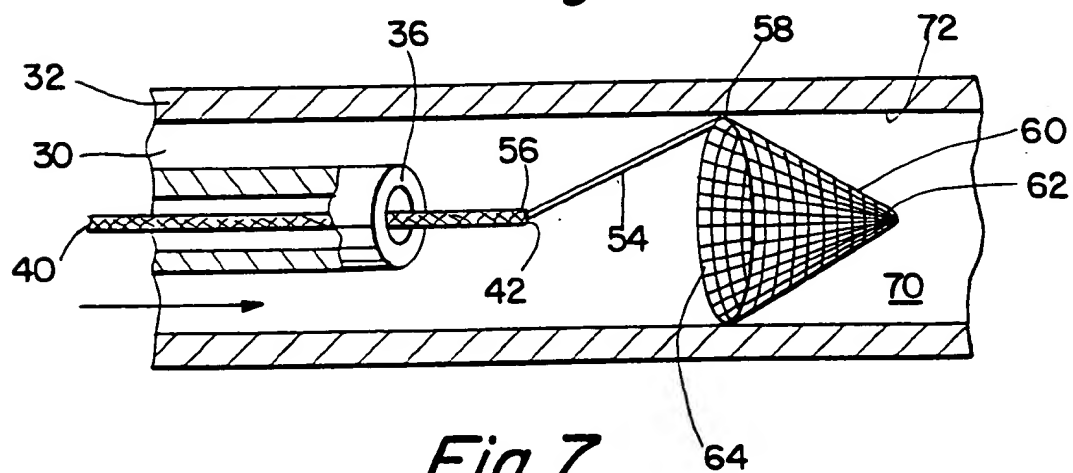


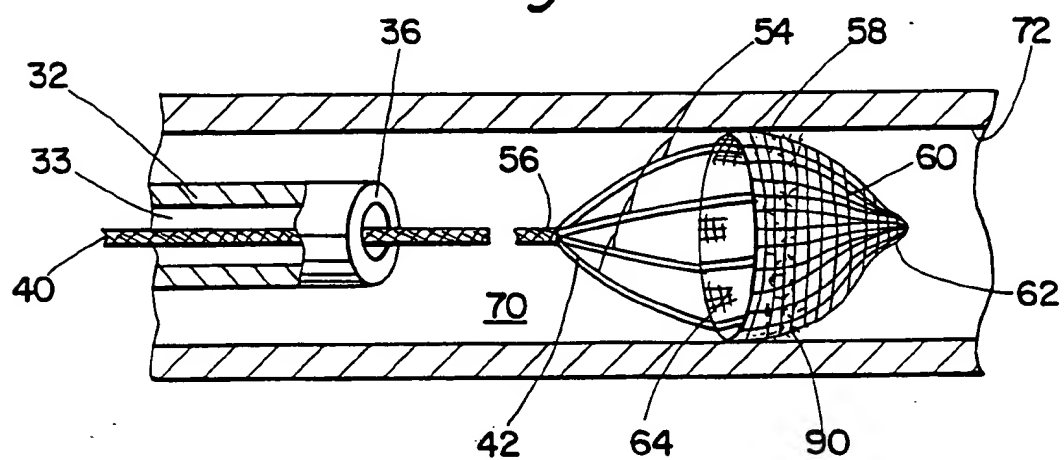
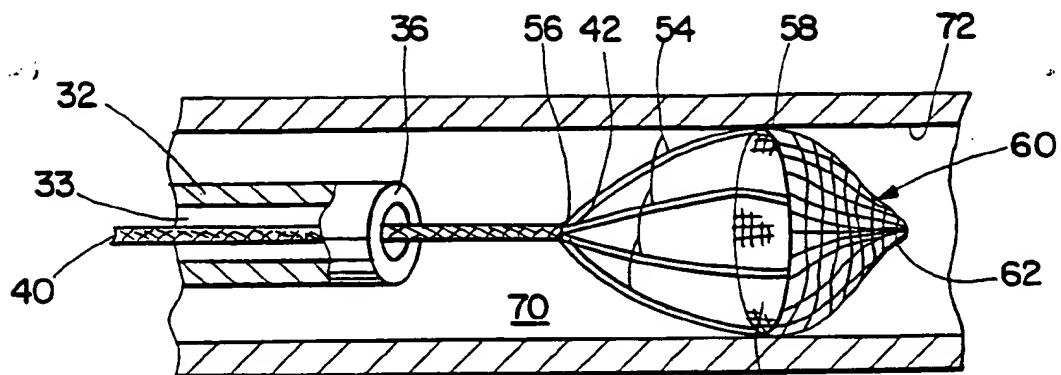
*Fig. 4B*



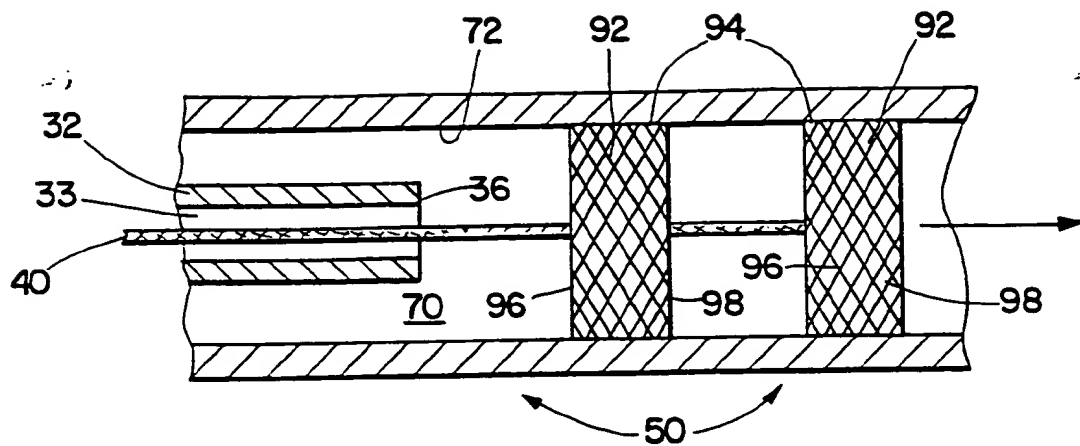
*Fig. 4C*



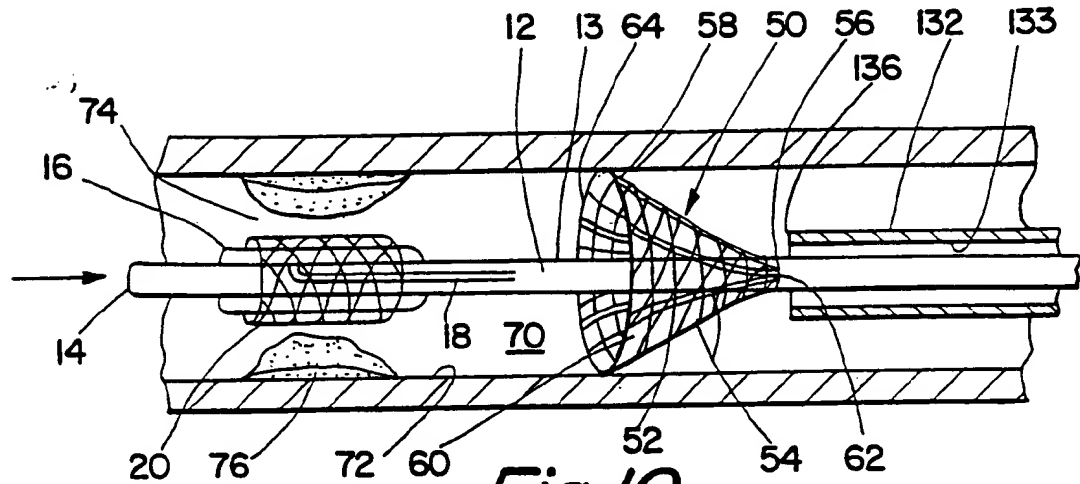
*Fig. 6A**Fig. 6B**Fig. 7*



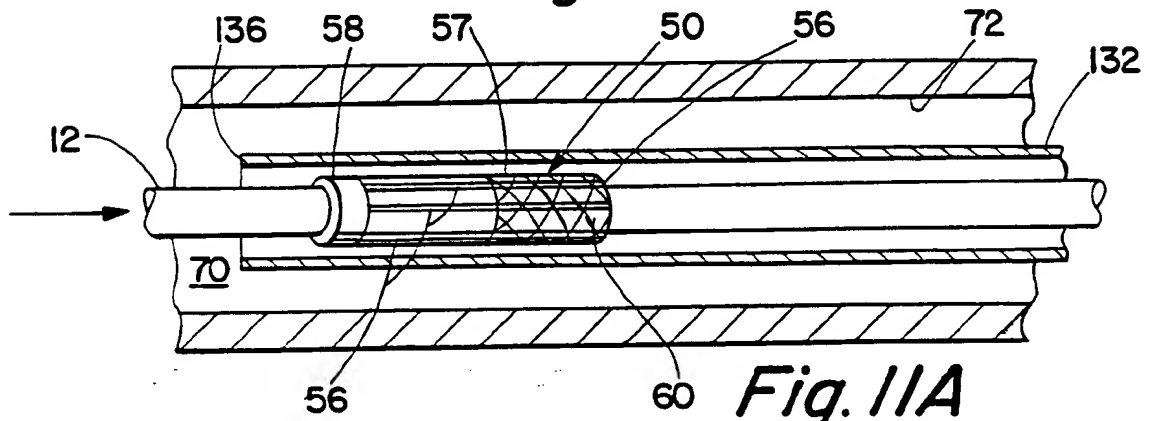




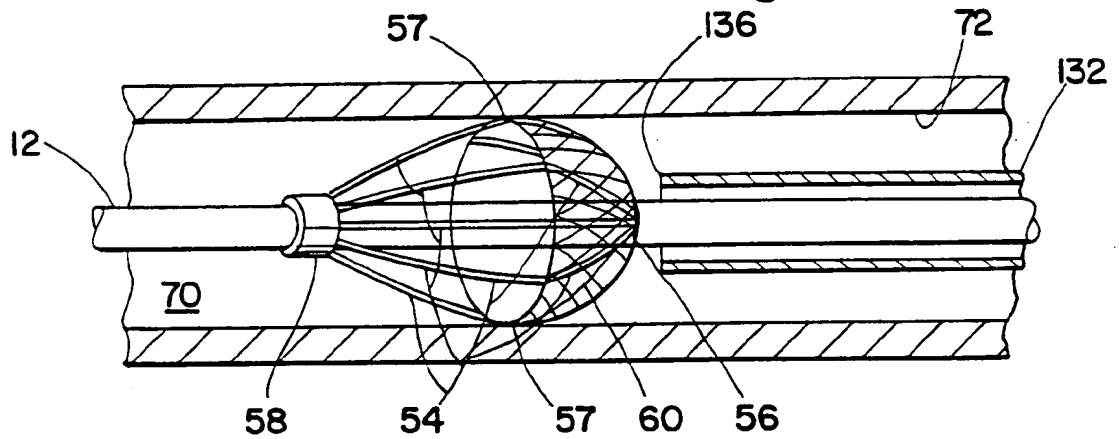
*Fig. 9*



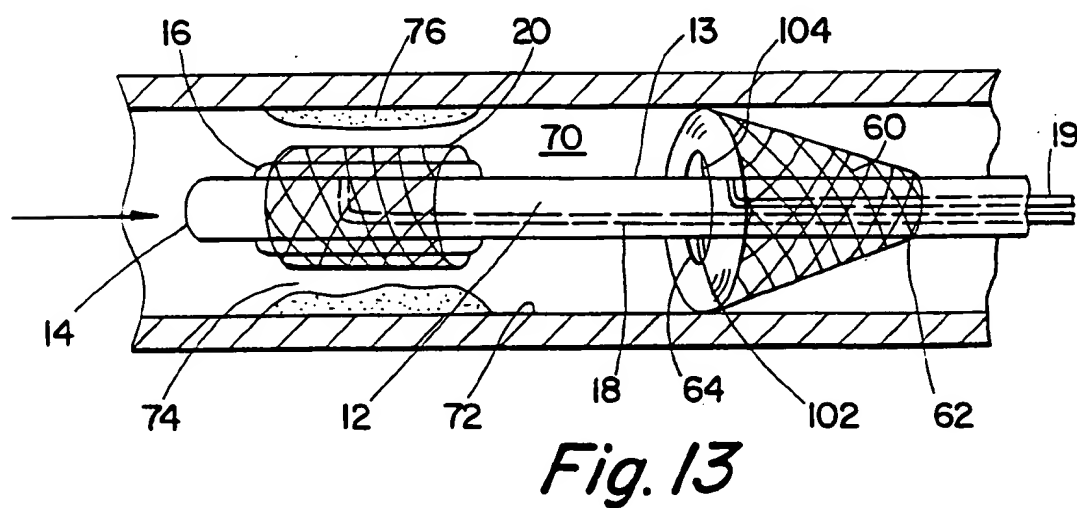
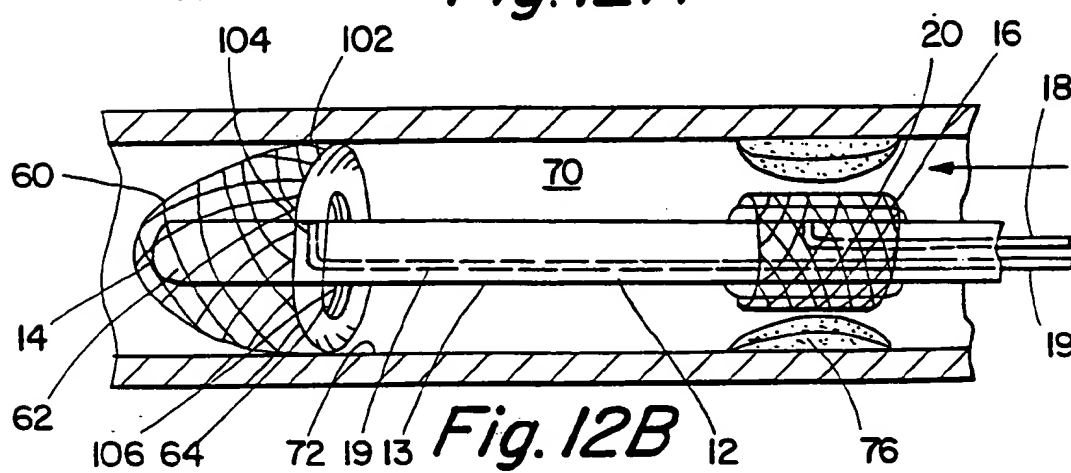
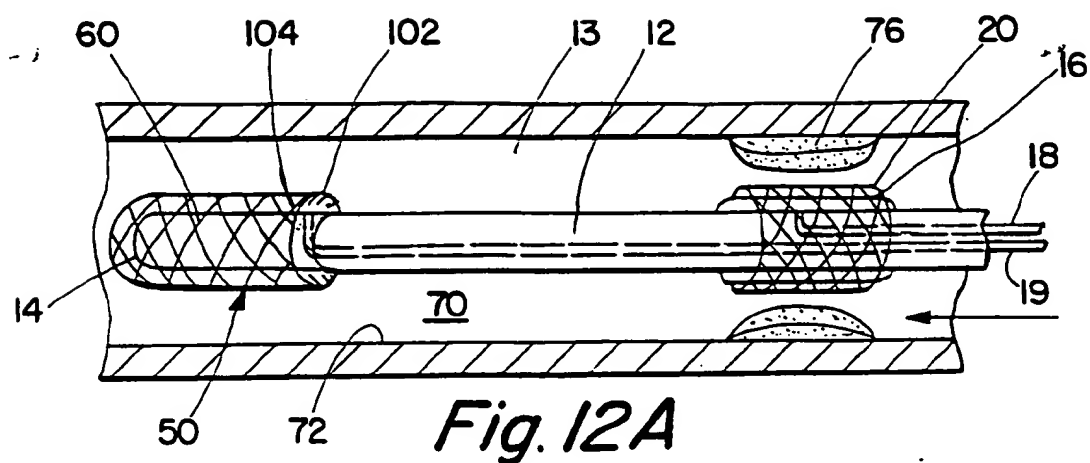
*Fig. 10*



*Fig. 11A*



*Fig. 11B*



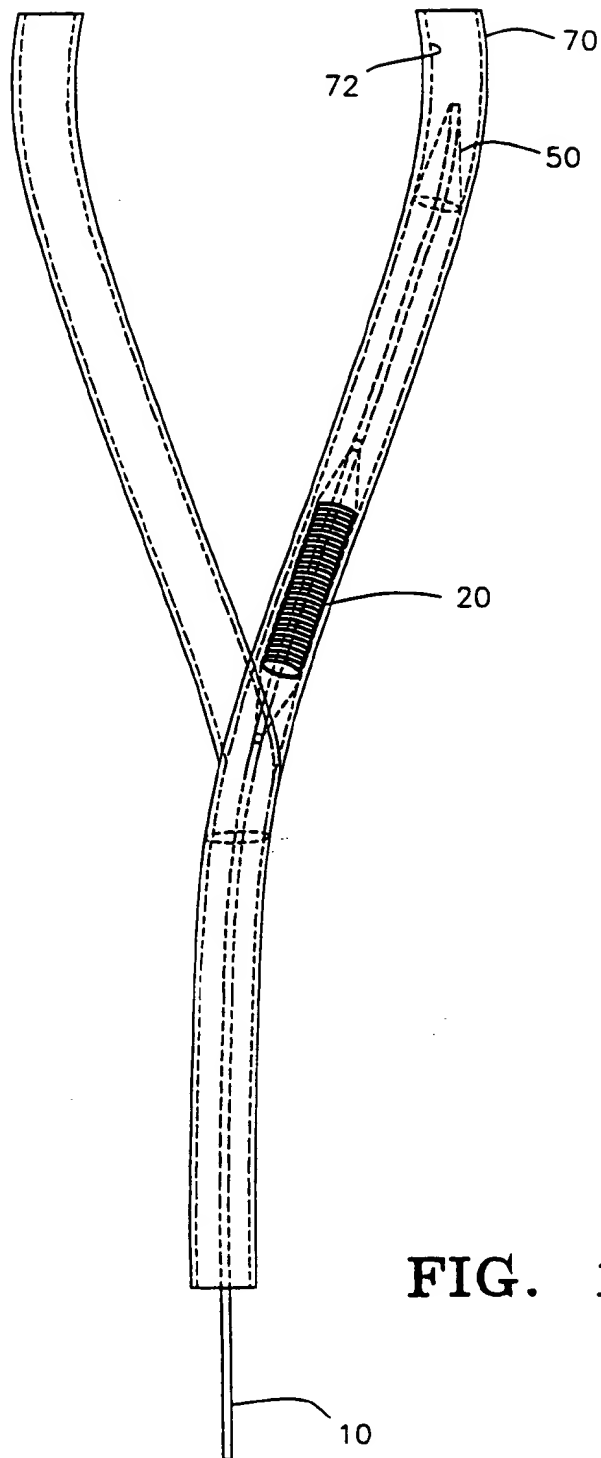


FIG. 14

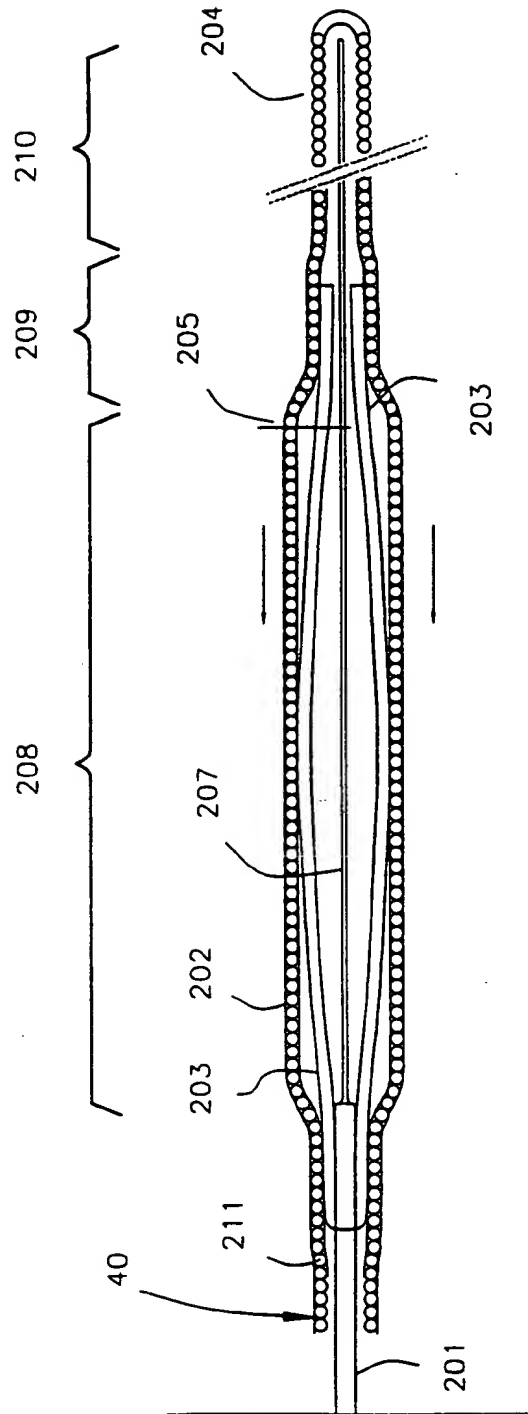


FIG. 15

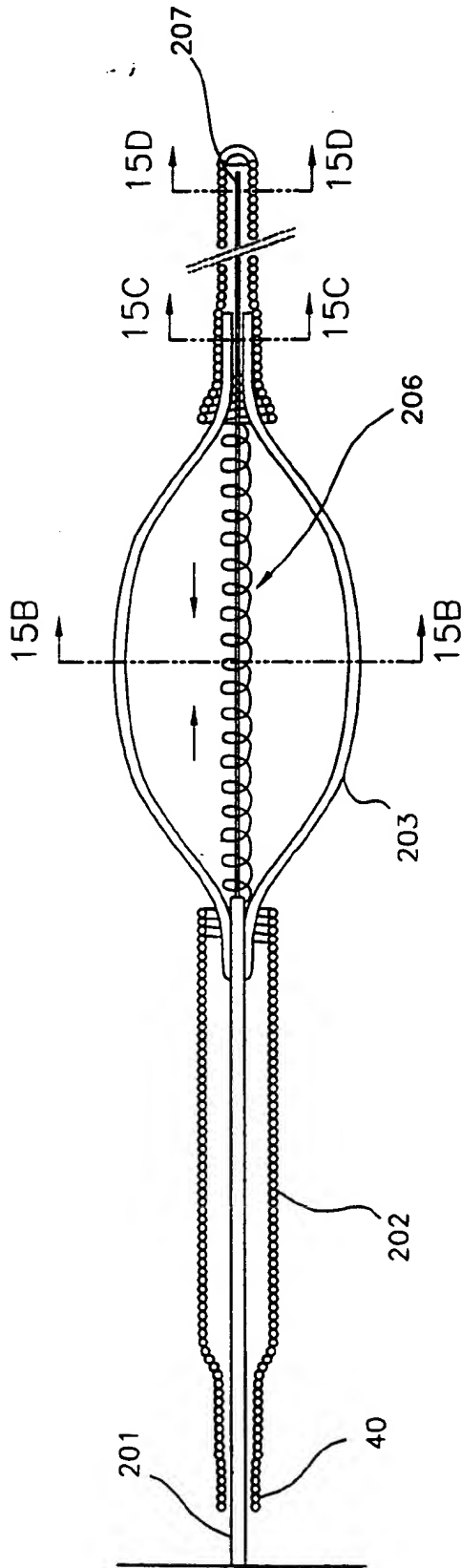


FIG. 15A

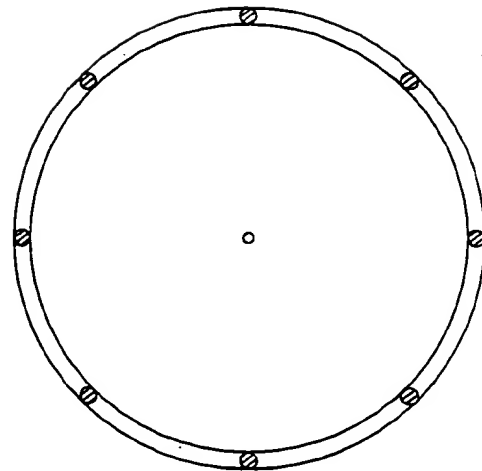


FIG. 15B

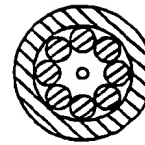


FIG. 15C

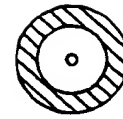


FIG. 15D

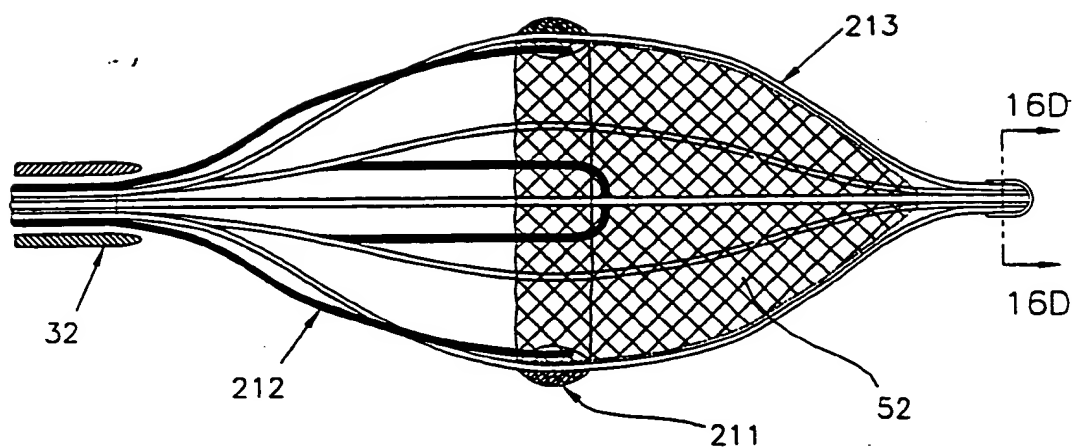


FIG. 16

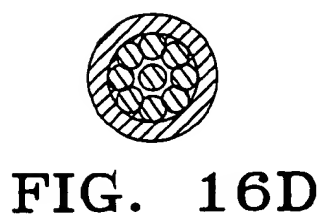


FIG. 16D

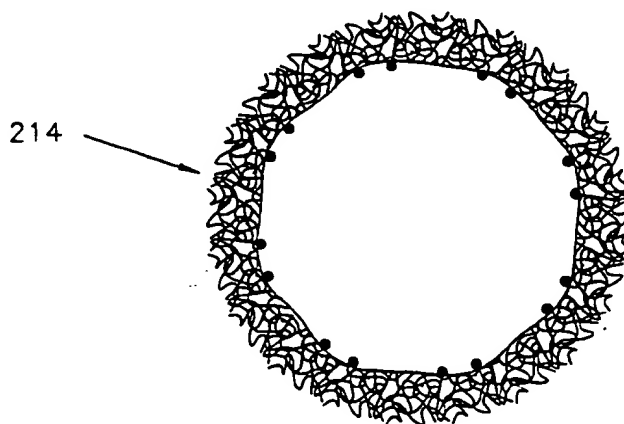


FIG. 16A

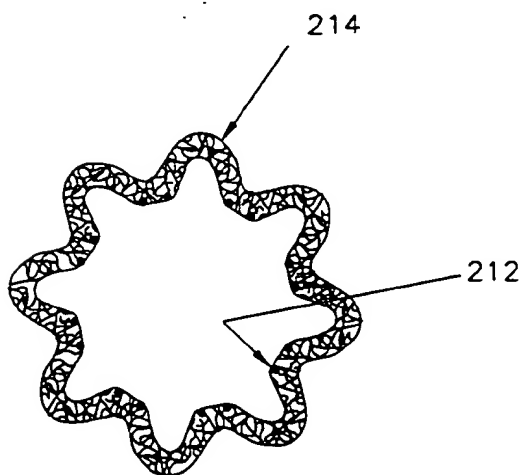


FIG. 16B

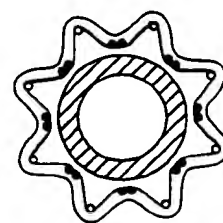


FIG. 16C

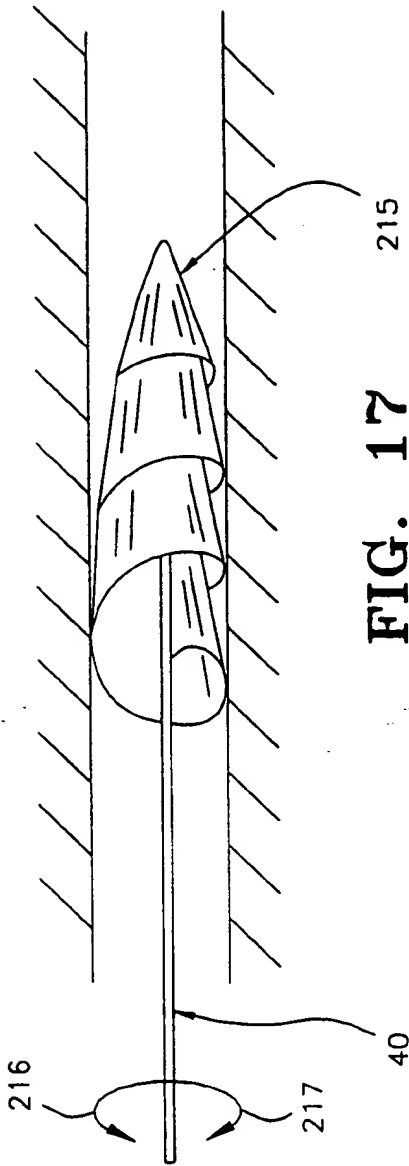


FIG. 17

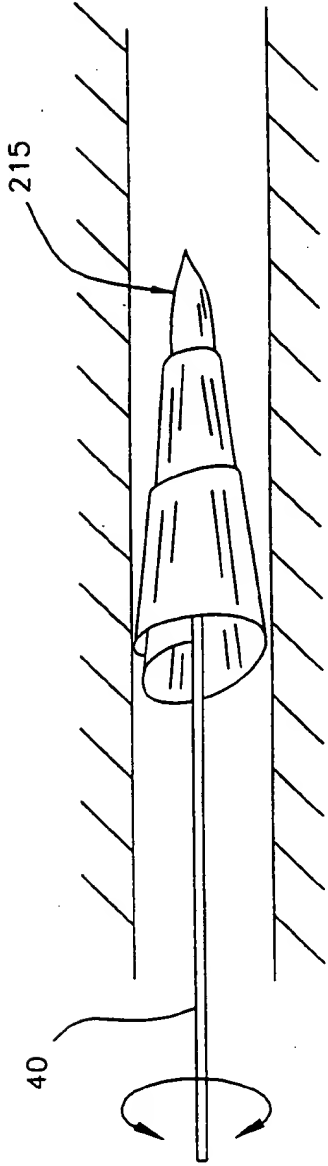


FIG. 17A



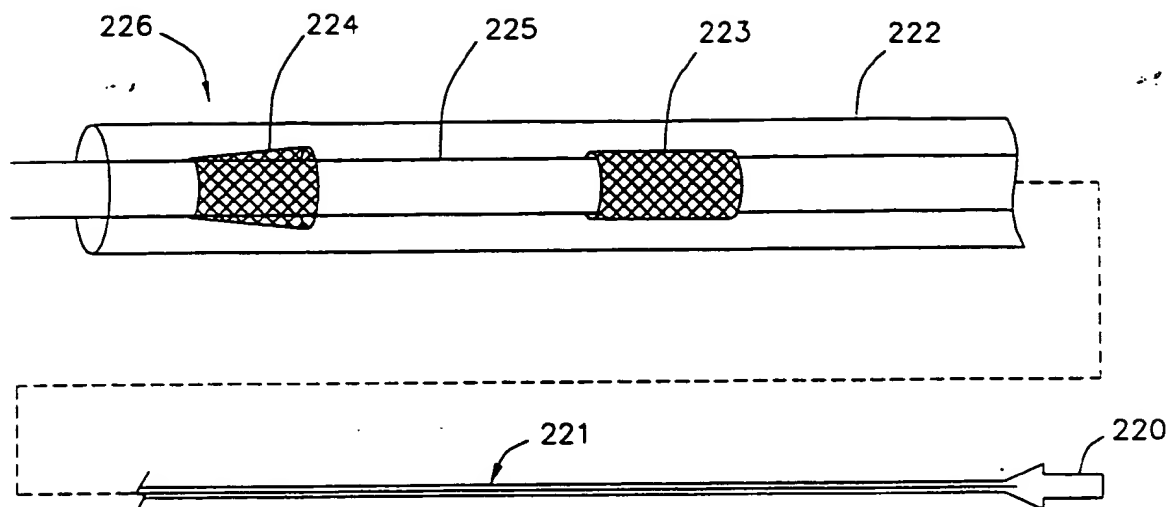


FIG. 18

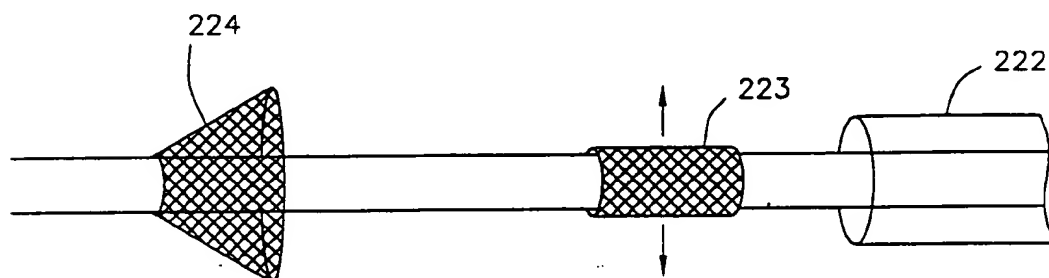


FIG. 18A

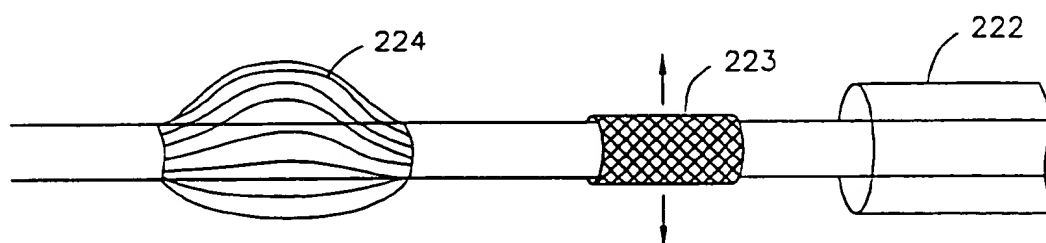


FIG. 18B

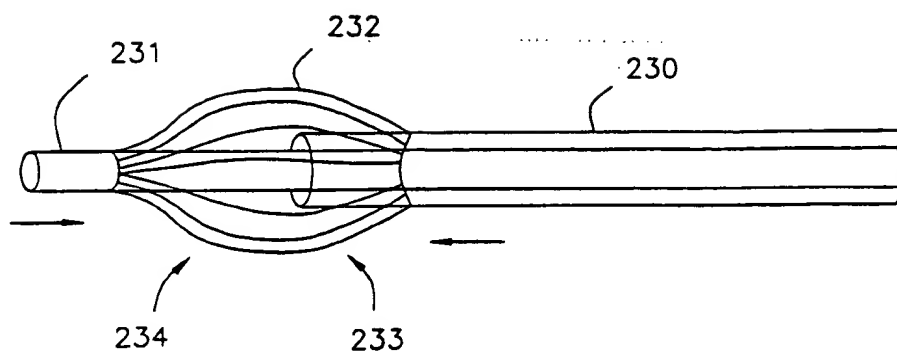


FIG. 19

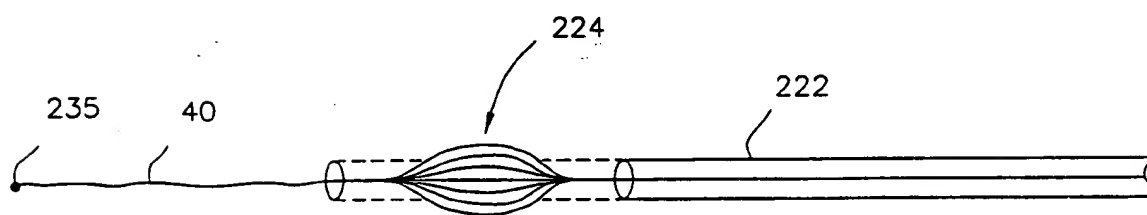
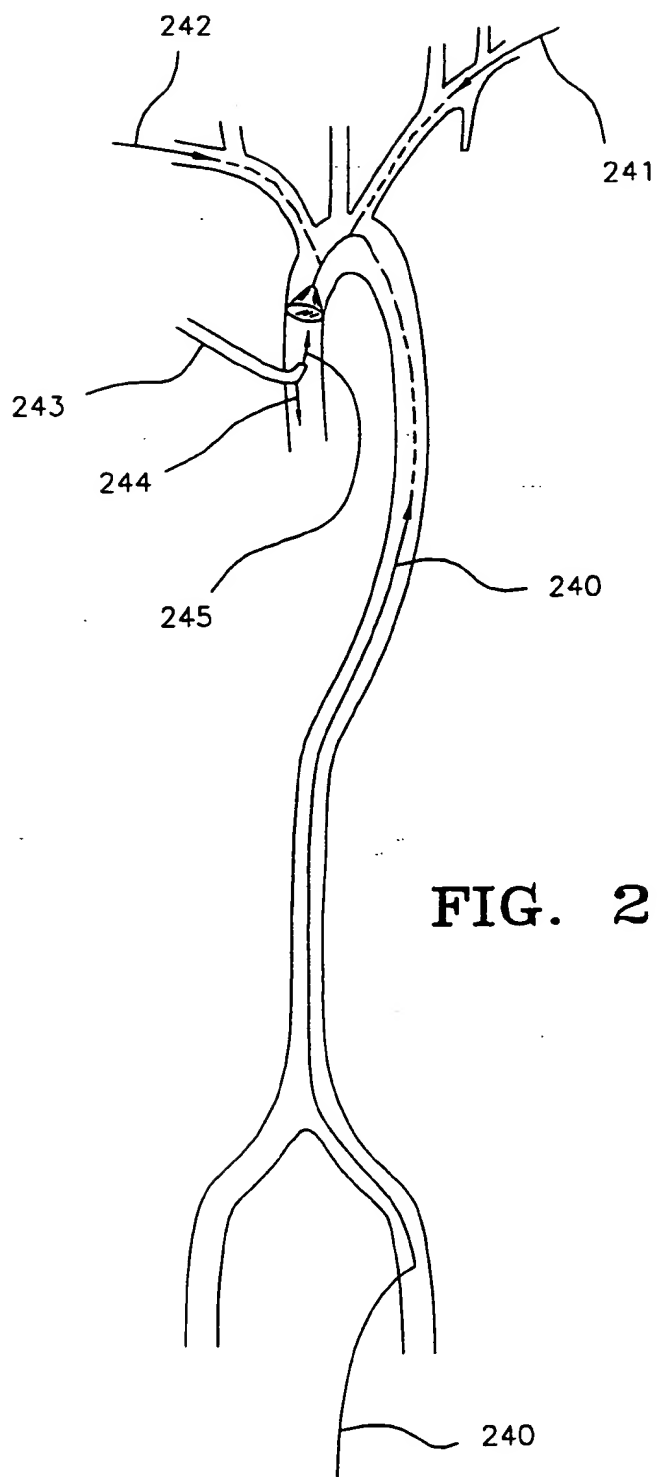


FIG. 20



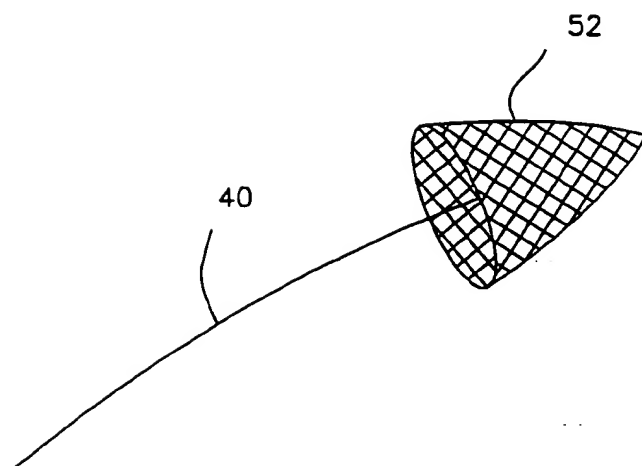


FIG. 22

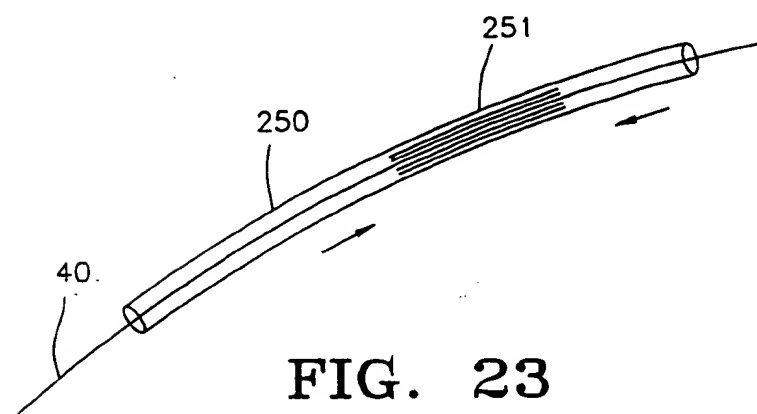


FIG. 23

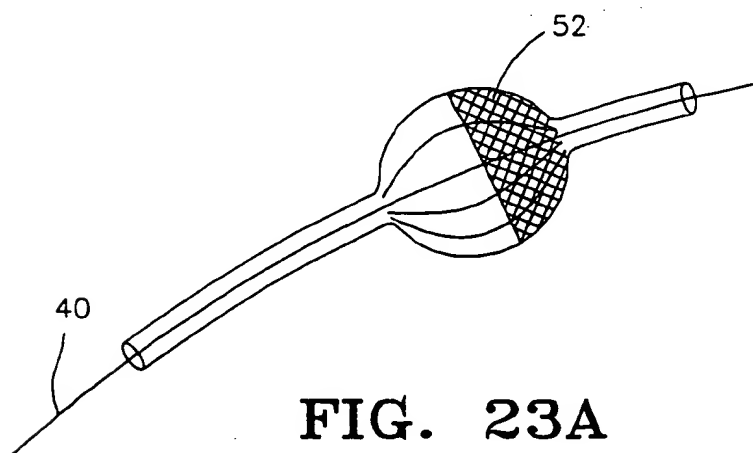


FIG. 23A

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US98/08920

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61M 29/00

US CL : 606/192, 194, 195, 198, 200

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/192, 194, 195, 198, 200

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
NONE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,549,626 A (MILLER et al) 27 August 1996, entire document.	1-86
A	US 4,873,978 A (GINSBURG) 17 October 1989, entire document.	1-86

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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*B* earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	
*O* document referring to an oral disclosure, use, exhibition or other means	
*P* document published prior to the international filing date but later than the priority date claimed	*A* document member of the same patent family

Date of the actual completion of the international search

08 JULY 1998

Date of mailing of the international search report

30 JUL 1998

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